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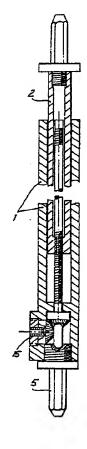
#### (57) Abstract

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A system of spinal roding of subcutaneous, compression and distraction rods which are used in the treatment of patients suffering from anomalies in the curvature of the spine. The distraction rods comprise an elongated housing (1) having located at one end a connection means (4) for a clamp (19) for connection to the vertebrae. An elongated member (2) is located in the housing (1) and is driven by drive means (10) to telescopically move within the housing (1). The other end of the elongated member containing a clamp support (4). In use the lid is extended in the clamps located in the required vertebrae and the drive means (10) operated to supply pressure to the vertebrae.



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#### DISTRACTION RODS

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The present invention relates to spinal rods, and in particularly, to an improved system of spinal roddling of subcutaneous, compression and distraction rods which are used in the treatment of patients suffering from anomalies in the curvature of the spine. The systems are inserted internally and are hooked onto the respective vertebrae to support the spine, to prevent such from growing incorrectly during child growth and initially give correction to both children and adolescents.

The prior art such as those shown in figure 1 comprise both spinal rods 16 and 17 which comprise a threaded rod 17 with a hook like connector 19 located at one end with a similar hook like connector 18 having an internal thread to engage on the threaded rod 17 to move up and down the threaded rod 17; the position of the second hook like connector being stabilised by a nut located on the threaded shaft. For insertion into the patient, a major operation is required to allow access to the spine for a length some distance greater than the total length of the rod. As the rods are also inserted in children, it is necessary, due to the growth of the child, that the hook like connections are adjusted to ensure correct contact with the respective vertebra, as the child grows. To allow for this adjustment, a section of the threaded rod must extend past the top hook like connector. However, to prevent this shaft from protruding through the patient's skin, it is necessary that only a small length of rod extend beyond the adjustable hook like connector.

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The rod 16 comprises a ratchet end 20 to allow for increase of the hook like connector to give the necessary distraction. Such is held by a clamp (not shown).

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The problem with these arrangements is that the patient's back must be opened to allow for adjustment of the rods, and the ratchets, or threads of the rods may have to be cleared of body tissue, such that the hook can be screwed or extended along ratchet to the new position to effectively hold the spine in the correct position.

Because of the nature of the operation, the patient usually suffers substantial trauma, due to the severity of the operation. Apart from the number of adjustments which are required when prior art rods are used, it is usual, during the growth period of a child that replacement operations of rods are required, due to the growth of the child and the necessity to keep increasing the length of the rods to take into consideration the increasing spacing between the respective vertebra.

The present invention seeks to ameliorate these disadvantages by providing a distraction rod comprising an elongated housing having located at one end a connection means for a clamp for connection to the vertebra, and having at the other end a second connection means for a clamp means for connection to the vertebra, which connection means is located on an elongated member which slidably fits within said elongated housing, said housing having operating means which, upon engagement, moves said elongated member longitudinally, with respect to said elongated housing.

The present invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a schemative representation of the prior art showing how it is used;

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Figure 2 shows an exploded view of one embodiment of the present invention;

Figure 3 shows a cutaway assembly view of the embodiment shown in Figure 2.;

Figure 4 illustrates another embodiment of the present invention; and

Figure 5 is a schematic representation of a prior art rod and a distraction rod according to one embodiment of the present invention, shown in use, not necessarily showing correct surgical placement into the spine.

A distraction rod made in accordance with one embodiment of the present invention is as shown in the figures 2 and 3 and comprises an elongated housing 1 into which an elongated member 2 slidably fits. The fit between the housing 1 and the member 2 is such to prevent the ingress of tissue and body fluids into the cavity 3 of the housing. Located at the top of the elongated member 2 is a connection 4, for the hook like vertebra connectors (not shown). The connectors 4 have a non circular connecting rod 5 to prevent the hook like connectors from rotating thereon. The profile of the connecting rods 5 can be any shape, such as rectangular, square, hexagonal, octagonal or elliptical.

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A drive rod 6 is inserted through the lower end 7 of the housing 1 to extend through the neck 8 into the cavity 3. The drive rod 6 has located at its lower end a bevel gear 9. The drive gear 10 is inserted through the opening 11 to engage the bevel gear 9 of the drive rod 6. A locking means 12 is inserted into the opening 11 to hold the drive gear 10 in position and to co-operate with the drive gear 10 to prevent the ingress of any tissue or body fluids into the gear housing 13.

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The drive rod 6 is threaded and mates with a complimentary threaded section 14 of the elongated member 2 (as shown in Figure 3). Connection 4 is inserted into the lower end 7 to seal said gear housing 13.

In use it is necessary that the patient's spine be exposed and that the vertebra hook like clamps (not shown) are connected to the respective connectors 4, and the drive gear operated to extend the elongated member 2 to position the vertebra clamps at the appropriate position, and the drive gear 10 is operated to correctly increase the distraction rod to the appropriate position needed for the patient. The drive gear 10 can be operated by any suitable connection, such as an Allen key socket 15, as shown in Figure 3. This socket would be positioned facing toward the patient's skin.

A further embodiment is shown in figure 4. This distraction rod is similar in construction to the previous embodiment providing further advantages over the prior art.

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However, the housing 1 has lands or growes 20 running the length of the housing 1, and the elongated member 2 has projections 21 which abut against the lands 20 or, fit within the grooves 20, to prevent rotation of the elongated member 2 with respect to the housing 1.

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The elongated member 2 has an internal threaded section (not shown) which engages the threads of the drive rod 6 similar to the previous embodiment.

Because of the non rotation of the elongated member 2 the hook connector 22, has a circular profile connector rod, suitable to receive standard spinal hooks.

The operation required to insert the spinal rods of the present invention would be similar in nature to that of the prior art rods. However, to increase the length of the spinal rod of the present invention, as shown in the Figure 5, a minor operation is required to expose the Allen key socket 15 as compared to the larger operation required in the prior art. An Allen key is fitted into the said socket to turn the drive bevel gear 10 which, in turn, rotates the drive rod 6 which interacts with the threaded section 14 of the elongated member 2 which, because the vertebra clamp is fixed with respect to the spine and is rotatably fixed to the connections 14, cause the elongated member 2 to be extended along the threads of the drive rod 6, extending the distance between the two vertebra There is no necessity to operate near the connection of the vertebra clamps to the spine, as is the case with the . prior art rods, as the only operation required is that to gain

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access to the Allen key socket, with regard to the "increasing section" of the future adjustment operations.

In order to allow the rod to be bent to fit the body contour at the top end, the manufacture would be as in figure 4 but having the housing 1 20mm shorter than that shown in figure 4 to allow for bending of the elongated member 2 without disturbing the mechanism; this being the preferred bending means.

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The rod does not extend to any appreciable distance beyond the vertebra clamps and, as the elongated member 2 is telescopically located with the housing 1, the rod can be continued to be used throughout the growth of the greater majority of children suffering from spinal disorders. Thus, rather than the children suffering major surgery many times in their life when a prior art rod is used, the children would only require one major operation to implant the distraction rod of the present invention, and minor operations to expose the drive connection to lengthen the rod. Therefore, the patients would be exposed to less trauma with the implantation of the present invention than with the existing devices.

In the prior art, to perform compression it is necessary to use a full threaded rod along which the hook like connectors are threaded in reverse positions and to adjust the position of the hook like connectors by means of respective nuts screwed along the threaded rod. The hook like connectors are positioned and the nuts tightened forcing the hook like connector towards each other to provide compression on the vertabra.

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In embodiments of the present invention, the distraction rod has to be modified to be used for compression. The top and bottom connectors 4 are removed and replaced with threaded sections of the required length. The hook like connectors are turned to face each other and are screwed along the respective threaded section to the appropriate locations and are held in place with nuts, or are simply slipped over the threaded section and are held in place by nuts. To apply compression the elongated member is withdrawn into the housing by means of the drive means forcing the hook like projections to move towards each other.

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In a further form of the invention there is provided a distraction rod which comprises:

an elongated member having at one end a connection means adapted to connect a vertebra clamp non rotatably thereto and provided at the other end with a threaded section;

a housing adapted to engage over said threaded section to interact and rotate along said threaded section, said housing being adapted to support a vertebra clamp rotatably thereon; and

a drive means adapted to engage with said housing such that, when said drive means is operated, said housing rotates and climbs along said threaded section, moving said vertebra clamp associated therewith.

Preferably the drive means is carried by said vertebra clamp, and the elongated member is of a diameter such that it can be bent to conform with the curvature of the patient's spine.

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The drive means can comprise any suitable connection, but preferably would be similar construction as to that described with the previous embodiment, utilising bevel gears or the like.

As the present invention is made from materials such as 316L medical grade stainless steel or titanium alloys which are inert to action from the tissue and body fluids, and the construction is such to prevent the ingress of tissue and body fluids between the moving surfaces, the present invention provides an improved spinal rod which possesses many advantages over those of the prior arts.

Embodiment of the present invention provide the following advantages over the prior art:

- No projection of the rod beyond the hook and as such the rod will not pierce the skin.
- 15 2. Reduction in rod exchanges, due to increased useable life of the rod.
  - 3. No thread or ratchet cleansing/dissecting of biological growth.
  - 4. Smaller adjustment operation.
- 20 5. Less scarring.

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- 6. May show greater control as can be adjusted more often.
- 7. Due to ease, increased usage to wider number of patients.
- 8. Smaller removal operation, no thread or ratchet cleaning.
- 9. Less patient trauma, hospitalisation, recuperation.
- 25 10. Finer increase of any given amount, rather than .27", in ratchet system, giving to better control of correction, both initially and subsequent.
  - 11. Due to fine increase, less neurological related problems.

- 12. Increase above lower hook at a central point, giving to less opening of wound by a large degree.
- 13. No need of re-opening of subcutaneous tissue on rod increases.
- 5 14. Can be bent and still increased, such not available in any prior system.
  - 15. Easier to place into purchase sites.
  - 16. Locks interiorally, alleviating need for 'C' clips or thread destroying.
- 10 17. Covers all fields in which both ratchet and threaded rods are used all parts may be exchanged for different applications.

It should be obvious that modifications could be made to the above description, such as the method of driving the drive gear and the type of engagement between the gears, without departing from the spirit and the scope of the present invention.

- 18. Can take child or adult hooks by exchanging the supports.
- 19. Less likelyhood of snapping and hence reducing the likelyhood of litigation.
  - 20. Less bending opportunity, after placement.
  - 21. No sharp edges.

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- 22. Inner shaft may be made to fit numerous hooks and still maintain its non pulling of flesh on increase.
- 23. For compression, hooks can be firstly placed and nuts introduced to maintain position, now rod may be decreased to effect desired compression, rather than continual nut movement.



- 25. Better ease of distraction during fusions, or compression.
- 26. To remove, can screw out of hooks, rather than snap rod, and again no need to clean ratchet/thread, of tissue growth.

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27. The rod has significant advantages over the ratchet and threaded systems, due to easier placement, easier removal, greater control, finer correction and patient alleviation of trauma. Such also being an advantage in patient not desiring rod increase.

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Following is a list of attachments for embodiments of the present invention:

- Seals (optional) Silastic or other suitable plastics
   material. All attachments have hexagonal removal section.
- 5 TOP
  - 2. Hook support round.
  - 3. Hook support 20mm longer round. (For bending.)
  - 4. Hook support round with thread section protruding some 1/8".
- 10 5. Thread Section (any length) for compression.
  - 6. Multi hook design.

## BOTTOM

- 7. Round hook support.
- Round 20mm longer hook support (bending)
- 9. Round hook support with thread of some 1/8" (Fractures).
  - 10. Square hook support.
  - 11. Square 20mm longer hook support.
  - 12. Square hook support with tread of some 1/8".
  - 13. Screw in thread compression section (any length).

### 20 TOOLS

- 14. Double end spanner.
- 15. Surgical driver.
- 16. Bending tool.

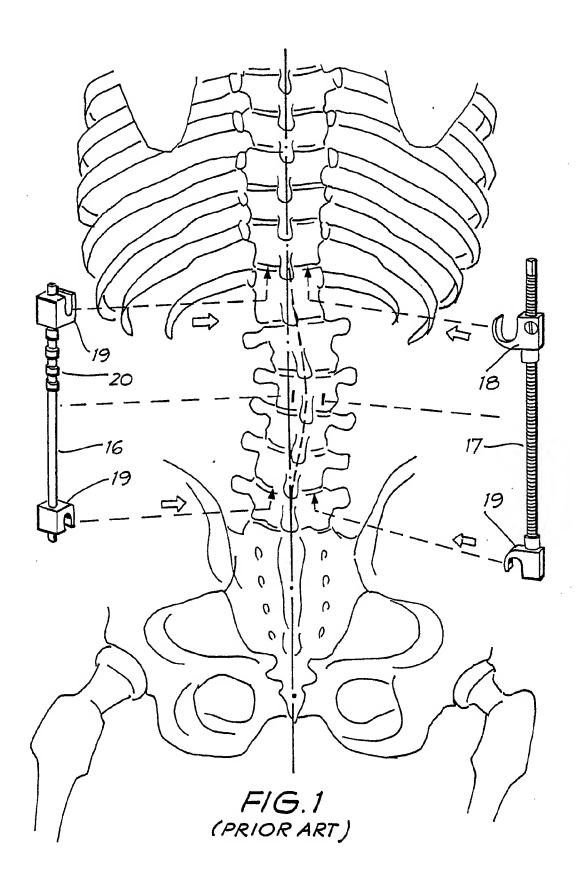
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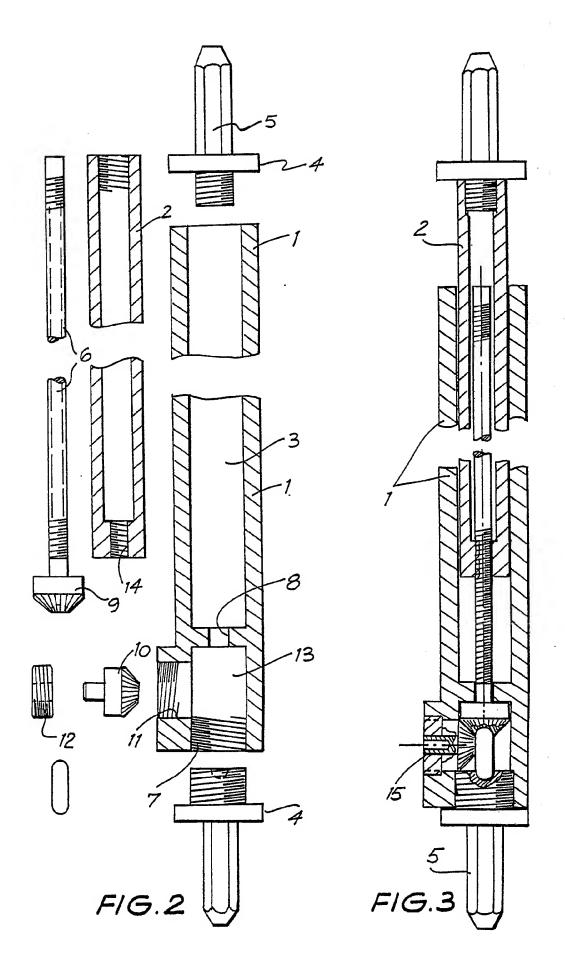
#### THE CLAIMS

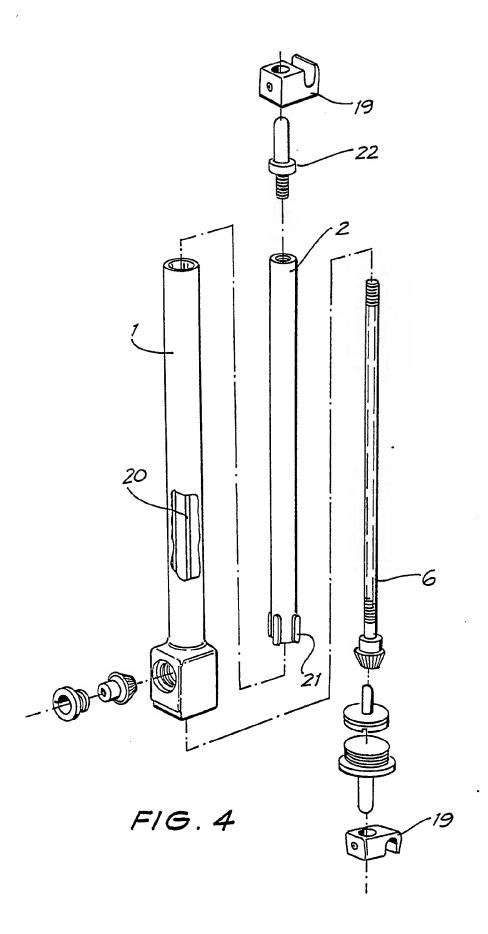
- 1. A distraction rod comprising an elongated housing having located at one end a connection means for a clamp for connection to the vertebra, and having at the other end a second connection means for a clamp means for connection to the vertebra, which connection means is located on an elongated member which slidably fits within said elongated housing, said housing having operating means which, upon engagement, moves said elongated member longitudinally, with respect to said elongated housing.
- 2. A distraction rod according to claim 1 wherein said elongated member has an oxial bone and said operating means comprises a threaded rod which fits within the bone of the elongated member and engages on a threaded section therein such that the elongated member can move along the threaded rod.
- 3. A distraction rod according to claim 2 wherein said operating means comprises a right angel drive.
- 4. A distraction rod according to claim 3 wherein said right angel drive comprises a level gear operable externally of the housing which meshes with a bend gear on one and the of the threaded rod.
- 5. A distraction rod according to claim 4 wherein said right angle drive is operated by an allen key.
- 6. A distraction rod comprises:

an elongated member having at one end a connection means adapted to connect a vertebra clamp non rotatably thereto and provided at the other end with a threaded section;

- a drive means adapted to engage with said housing such that, when said drive means is operated, said housing rotates and climbs along said threaded section, moving said vertebra clamp associated therewith.
- 7. A distraction rod according to claim 5 wherein said drive means is a right angle drive.
- 8. A distraction rod substantially as hereinbefore described with reference to figure 2 and 3 or figure 4 of the accompanying drawings.







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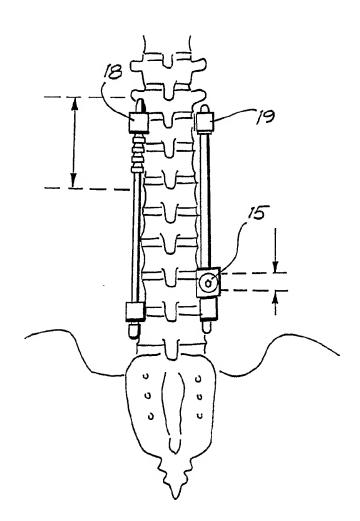


FIG. 5

## INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 87/00160

I. CLASS	FICATION OF SUBJECT MATTER (1 several classification symbols apply, indicate this s	
	to International Patent Classification (IPC) or to both National Classification and IPC	
I I	nt. Cl. <sup>4</sup> A61B 17/60	
II. FIELDS	SEARCHED	
	Minimum Documentation Searched 7 Classification Symbols	
Classification	in System Gesanication Cymsos	
I	PC A61B 17/60, 17/18, 17/56	
	Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched 4	
A	U: IPC as above	
III. DOCL	MENTS CONSIDERED TO BE RELEVANT	Relevant to Claim No 12
Category *	Citation of Document, 11 with indication, where appropriate, of the relevant passages 12	Referent to Clean to
X	DE,A, 3434753 (FRAUNHOFER-GES FORD ANGE) 19 September 1985 (19.09.85)	1
A	Derwent Abstract Accession No. H7053X/35, Class P31 SU,A, 485-739 (CRIMEAN MEDICAL COL) 22 December 197 (22.12.75)	5 1
A	Derwent Abstract Accession No. 86-345138/52, Class P31, SU,A, 1228-843 (MOSC CLINICAL RES) 7 May 1986 (07.05.86)	
A	Derwent Abstract Accession No. 86-303606/46, Class P31, SU,A, 1219-070 (IKUT TRAUMA ORTHOP) 23 March 1986 (23.03.86)	
"E" "U" "P"  IV. CI	cited to understand the principal state of the art which is not considered to be of particular relevances. Its document but published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means other means are than the priority date claimed occument published prior to the international filing date but later than the priority date claimed occument is complied with ments, such combination being the priority date claimed of the same o	rance: the claimed invention or cannot be considered to or cannot be considered to vance: the claimed invention live an inventive step when the one or more other such docume obvious to a person skilled me patent family
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# ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL APPLICATION NO. PCT/AU 87/00160

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Patent Document Cited in Search Report			Patent Family Members				
DE	3434753	EP	173725	WO	8504096		
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## PCT

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(81) Etats désignés: AT (brevet européen), BE (brevet européen), CH (brevet européen), DE (brevet européen), DK (brevet européen), ES (brevet européen), FR (brevet européen), GB (brevet européen), IT (brevet européen), LU (brevet européen), NL (brevet européen), SE (brevet européen), US.

#### Publiée

Avec rapport de recherche internationale. Avant l'expiration du délai prévu pour la modification des revendications, sera republiée si de telles modifications sont

(54) Title: A SUPPORTING DEVICE FOR THE SPINAL COLUMN

(54) Titre: DISPOSITIF D'ETAIEMENT DU RACHIS

#### (57) Abstract

The invention concerns an instrument, which is screwed into the different vertebra, for reducing or containing spinal curvature by means of several screws interconnected by a notched connecting element permitting a micrometric adjustment of the different screws between themselves after final blocking effected by a cap-covered bolt. The instrument consists of two or several screws (1) having a thread on the lower U-shaped diapason part (3) in which a notched (14) interlocking element (6) is placed which is blocked by a bolt (4) covered by a pierced (16) cap (5), thus ensuring that the U-edges do not come apart when the bolt (4) is tightened. The instrument is designed to reduce and contain spinal curvature.

#### (57) Abrégé

L'invention concerne une instrumentation permettant après vissage pédiculaire dans les différentes vertèbres de réduire et contenir le rachis au moyen de plusieurs vis reliées entre elles par un élément de solidarisation cranté per-

mettant un réglage micrométrique des différentes vis entre elles après blocage définitif par un boulon recouvert d'un capuchon. Cette instrumentation est constituée de deux ou plusieurs vis (1) présentant un filetage à leur partie inférieure, un diapason en forme de U (3) dans lequel vient se poser un élément de solidarisation (6) cranté (14) bloqué par un boulon (4) recouvert d'un capuchon (5) percé (16) évitant lors du serrage du boulon (4) que les bords du U ne s'écartent. Cette instrumentation est destinée à réduire et contenir le rachis.

## UNIQUEMENT A TITRE D'INFORMATION

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## Dispositif d'étaiement du rachis

La présente invention concerne un dispositif permettant, par implantation d'une instrumentation rachidienne par vis diapason, de contenir, réduire, s'adapter et rétablir les courbures physiologiques du rachis, au moyen de plusieurs vis dont la tôte en forme de U permet de recevoir un élément de de solidarisation des différentes vis entre elles.

Habituellement, on implantait des vis pédiculaires réunies par des plaques. De ce fait, on était dépendant de l'écartement des trous des plaques. D'où une bonne cotention mais une faible réduction.

On implantait aussi des crochets posés sur les arcs postérieurs évaluants sur des tiges avec des systèmes de blocage complexes. Ces systèmes permettent une bonne réduction et une bonne contention mais exigent d'une part le respect des arcs postérieurs vertébraux, et d'autre part des manoeuvres délicates de va et vient dangereuses pour le patient et peu pratiques pour l'opérateur.

Le dispositif selon l'invention permet de remédier à tous ces inconvénients. Il comporte en effet plusieurs vis composés de trois segments ; pointe-corpstête particuliers, d'un boulon, d'un capuchon, et d'un élément de solidarisation homolatéral.

La structure et la conformation de ce matériel a été spécialement crée à cet effet.

La vis est construite dans des matériaux homologués pour la chirurgie afin d'éviter les ruptures du matériel au niveau de sa pénétration dans le corps vertébral.

La pointe de la vis est de forme carrée pyramidale renversée. Le corps de la vis de forme cônique est porteur d'un filetage de type cortical qui permet un meilleur blocage de l'implant dans la région la plus fragile du pédicule vertébral.

De plus, cette conicité renforce la solidité du corps de la vis au niveau de la tête de vis.

La tête de la vis a une forme de diapason en U pour recevoir l'élément de solidarisation des diffférentes vis entre elles. Le fond du U est légèrement arrondi pour permettre de fixer l'élément de solidarisation dans plusieurs positions ; ce qui facilite aussi le blocage de l'élément de solidarisation.

Le U est fileté au niveau de la partie interne des branches pour permettre

## FEUILLE DE REMPLACEMENT

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le vissage in situ d'un boulon vérouillant l'élément de solidarisation. Le risque de ce système étant l'écartement des branches du U lors du vissage, on y remédie par la mise en place d'un capuchon venant parfaitement s'adapter sur la partie extérieure lisse des branches du U. Ce capuchon comporte un orifice circulaire pour permettre le serrage et le blocage définitif du boulon bloquant la tige de solidarisation.

Le boulon se caractérise par une forme cylindrique filetée portant à son extrémité une pointe cônique mâle venant s'adapter parfaitement dans les crans coniques femelles de la tige de solidarisation. La partie opposée du boulon comportant une cavité de forme hexagonale lui permettant de recevoir une clef de serrage.

L'élement de solidarisation est dans un matériau homologué pour l'implantation chirurgicale. C'est une tige de section cylindrique d'un diamètre suffisant pour résister aux contraintes et efforts du rachis, crantée pour permettre un réglage micrométrique des différentes vis entre elles. Chaque cran est de forme cônique femelle pour recevoir la pointe du boulon. Suivant le réglage à obtenir le crantage sera d'un pas variable.

Le diamètre de l'élément de solidarisation suffit à le rendre résistant tout en permettant un modelage aisé pour s'adapter ou rétablir les courbures physiologiques du rachis. De plus, sa section circulaire permet la rotation avant son verrouillage celui-ci se faisant après un positionnement correct de l'élément de solidarisation en serrant le boulon des différentes vis homolatérales.

Cette tige est de mise en place facile du fait de la conformation des têtes de vis car elle peut être positionnée directement au fond du U sans mouvement forcé ni nécessité de coulissage par va et vient.

La structure même de l'implant diapason permet en modifiant la taille de la vis ou en adaptant la tête de vis à d'autres systèmes d'ostéosynthèse de l'arc postérieur de pratiquer des fixations vertébrales sur toute la hauteur du rachis quels que soient le niveau et le type de vertèbres instrumentées en conservant le même élément de solidarisation.

Le dispositif représenté sur la fig 1 comporte deux vis côniques (1) avec une pointe (2), un corps (1) un diapason en forme de U (3), un boulon (4), un capuchon (5), un élément de solidarisation (6).

Le dispositif représenté sur les fig. 2a et 2b comporte une vis cônique de type cortical (1) avec une pointe carrée (2) à son extremité inférieure.

3

Le corps de la vis (1) comporte une double conicité : à savoir, conicité de l'âme de la vis (7) différente de celle du sommet du filet (8). La tête diapason en forme de U (3) est reliée au corps de la vis par un rayon (9) renforçant la solidité du corps de la vis au niveau de sa jonction avec le pédicule vertébral. Le fond du U est légèrement arrondi (10) pour permettre un blocage multi-axial de l'élément de solidarisation (6). Le diamètre supérieur du U (3) est plus petit à sa partie supérieure qu'à la partie inférieure. Ceci permettant de recevoir par ajustement glissant le capuchon (5).

La partie intérieure du U est filetée (11) et reçoit un boulon (4) permettant le blocage de l'élément de solidarisation.

Le dispositif représenté sur la fig 3 comporte un boulon (4) avec à son extrémité inférieure une partie cônique (12) ; une partie cylindrique file-tée (13) venant se visser dans le corps du U (3) en s'adaptant aux filets (11).

La partie cônique (12) vient s'adapter à la partie cônique femelle (14) de l'élément de solidarisation (6).

La partie supérieure du boulon (4) comporte une cavité hexagonale creuse (15) permettant de recevoir une clef de serrage.

Le dispositif représenté sur la fig.4 comporte un élément de solidarisation (6) des différentes vis des fig. 2-3-4.

Cet élément de solidarisation (6) est de section cylindrique.

Cet élément de solidarisation (6) est cranté (14) pour permettre le réglage micrométrique à l'aide du boulon (4) des différentes vis entre elles. Les crans de forme cônique femelle (14) reçoivent la pointe du boulon (12). Le dispositif représenté sur les fig. 5a et 5b comporte un capuchon (5) cylindrique venant s'adapter par glissement serré sur le sommet du U (3). La partie supérieure comporte un orifice (16) permettant le passage de la clef de serrage du boulon (4).

WO 90/09156 PCT/FR90/00096

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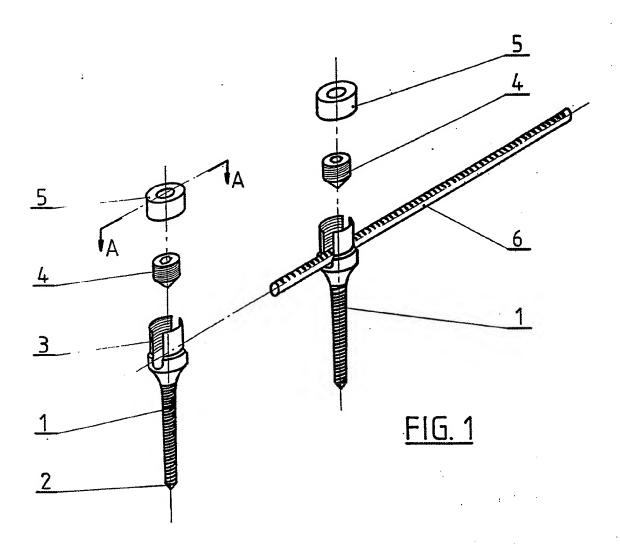
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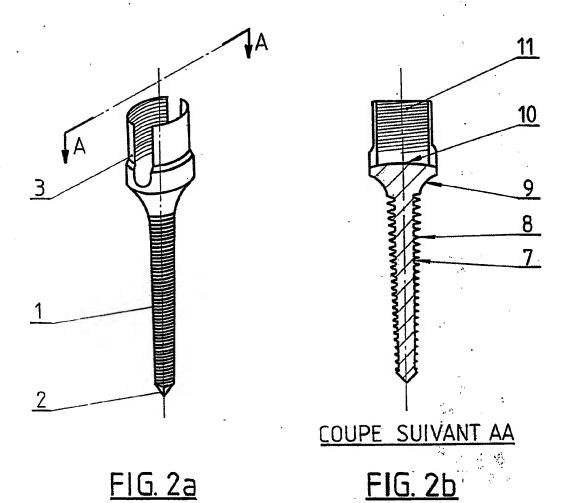
1) Instrumentation caractérisée en ce qu'elle comporte, pour réduire et contenir le rachis, plusieurs vis (1) présentant une tête en forme de U (3) filetée à l'intérieur de laquelle se pose l'élément de solidarisation (6) bloqué par un boulon (4) le tout recouvert d'un capuchon (5) sur la partie supérieure.

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- 2) Instrumentation selon la revendication 1 caractérisée en ce que la vis
- (1) comporte une conicité différente entre l'âme de la vis (7) et le sommet des filets (8).
- 3) Instrumentation selon la revendication 1 caractérisée en ce que la partie supérieure de la vis est un diapason en forme de U (3) fileté à l'intérieur (11) et lisse de section réduite au sommet du U par rapport à la base.
- 4) Instrumentation selon la revendication 1 ou la revendication 3 caractérisée en ce que le fond du U est arrondi (10) dans les deux plans.
- 5) Instrumentation selon l'une quelconque des revendications précédents caractérisée en ce que la partie reliant la vis (1) au diapason en forme de U (3) est un arrondi de forme concave (9).
- 6) Instrumentation selon les revendications précédentes caractérisée en ce que la base du boulon (4) est de forme cônique mâle (12) venant se coapter dans les crans (14) de l'élément de solidarisation (6), après serrage de celui-ci dans la tête de vis diapason en forme de U (3).
- 7) Instrumentation selon les revendications précédentes caractérisée en ce que la partie intérieure du capuchon (5) vient s'adapter par glissement dur dans la partie de moindre diamètre de la tête de vis diapason en forme de U (3) afin d'éviter que celle-ci ne s'écarte lors du blocage de l'élément de solidarisation (6). La partie supérieure du capuchon (5) est perçée d'un orifice circulaire (16) permettant le passage d'une clef venant s'adapter dans la partie supérieure du boulon (15) afin de bloquer définitivement après mise en place de tous les éléments, la tige de solidarisation (6).
- 8) Instrumentation selon les revendications précédentes caractérisée en ce que l'élément de solidarisation (6) est une tige de section cylindrique comportant des crans de forme côniques (14) situés sur la périphérie de la tige dans lesquels vient se bloquer la partie inférieure du boulon (12). Ces crans (14) usinés selon différents pas permettent un réglage micrométrique des différentes vis entres elles.

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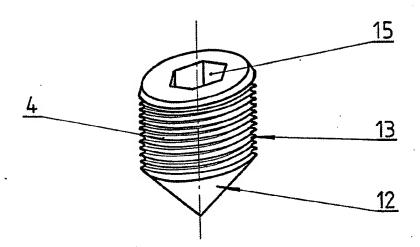
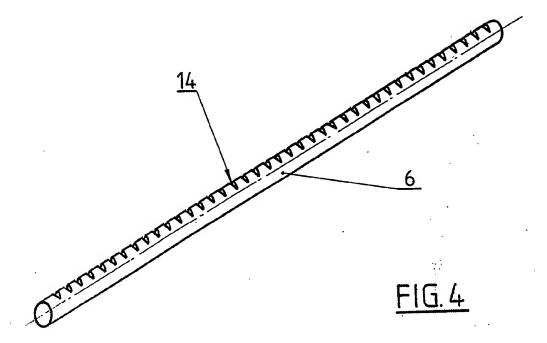
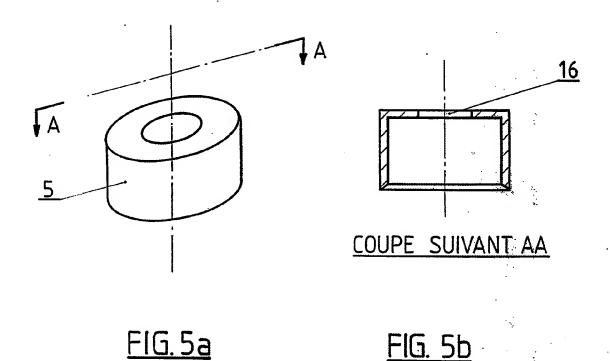


FIG. 3



FEUILLE DE REMPLACEMENT



## INTERNATIONAL SEARCH REPORT

International Application No

PCT/FR 90/00096

I. CLASS	SIFICATIO	N OF SUBJECT MATTER (if several classic	ication symbols apply, indicate all) *	
According	to Internat	ional Patent Classification (IPC) or to both Nati	onal Classification and IPC	
	c1. <sup>5</sup>	A61F5/02 ; A61B17/58		
II. FIELDS	S SEARCI	1ED		• •
		Minimum Documen	station Searched 7	
Classification	on System		Classification Symbols	
Int.	c1. <sup>5</sup>	A61B ; A61F		
		Documentation Searched other to the Extent that such Documents	han Minimum Documentation are included in the Fields Searched <sup>s</sup>	
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III. DOCU	JMENTS (	ONSIDERED TO BE RELEVANT		,
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FR 9000096

SA 34719

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(51) Internationale Patentklassifikation 5:

(11) Internationale Veröffentlichungsnummer:

WO 91/01115

A61B 17/58

A1

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7. Februar 1991 (07.02.91)

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19. Juli 1990 (19.07.90)

(30) Prioritätsdaten:

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20. Juli 1989 (20.07.89)

DE

(71)(72) Anmelder und Erfinder: BIEDERMANN, Lutz [DE/ DE]; Am Schäfersteig 8, D-7730 Villingen (DE). HARMS, Jürgen [DE/DE]; Belchenweg 9, D-7517 Waldbronn-Reichenbach (DE).

(74) Anwalt: PRÜFER, Lutz, H.; Harthauser Straße 25d, D-8000 München 90 (DE).

(81) Bestimmungsstaaten: AT (europäisches Patent), BE (europäisches Patent), CA, CH (europäisches Patent), DE (europäisches Patent)\*, DK (europäisches Patent), ES (europäisches Patent), FR (europäisches Patent), GB (europäisches Patent), IT (europäisches Patent), JP, KR, LU (europäisches Patent), NL (europäisches Patent), SE (europäisches Patent), US.

Veröffentlicht

Mit internationalem Recherchenbericht.

Vor Ablauf der für Anderungen der Ansprüche zugelassenen Frist. Veröffentlichung wird wiederholt falls Anderungen eintreffen.

(54) Title: PEDICLE SCREW AND PEDICLE-SCREW HOLDER

(54) Bezeichnung: AUFNAHMETEIL FÜR EINE PEDIKELSCHRAUBE UND PEDIKELSCHRAUBE

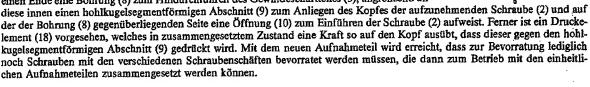
#### (57) Abstract

Disclosed is a pedicle-screw holder designed to be linked by joint with a screw (2) having a threaded shaft (3) and a sphere-segment head (4) and with a rod (16). In order to lower the cost of stocking screws of different shaft lengths and shaft diameters, the holder has a holder space (7) inside it, at one end of which is a bore (8) through which the threaded shaft (3) passes and, adjacent to the bore, on the inside, a hollow sphere-segment section (9) against which the head of the screw (2) to be held rests, and at the end remote from the bore (8) an opening (10) through which the screw (2) can be inserted. The invention also calls for a pressure element (18) which, when screw and holder are assembled, hexerts a force on the screw head such that the head is pressed against the hollow sphere-segment section. The new holder means that only screws with very different shaft dimensions have to be stocked since screws can be inserted in common holders.

#### (57) Zusammenfassung

Es wird für eine Pedikelschraube ein Aufnahmeteil zum gelenkigen Verbinden mit einer einen Gewindeschaftteil (3) und einen kugelsegmentförmigen Kopf (4) aufweisenden Schraube (2) einerseits und einer Stange (16) andererseits geschaffen. Damit die Bevorratung für Schrauben unterschiedlicher Schaftlänge und Schaftdicke bezüglich der Kosten verbessert werden kann, weist der Aufnahmeteil einen Aufnahmeraum (7) im Inneren auf, der an seinem einen Ende eine Bohrung (8) zum Hindurchführen des Gewindeschaftteiles (3), angrenzend an

der der Bohrung (8) gegenüberliegenden Seite eine Öffnung (10) zum Einführen der Schraube (2) aufweist. Ferner ist ein Druckelement (18) vorgesehen, welches in zusammengesetztem Zustand eine Kraft so auf den Kopf ausübt, dass dieser gegen den hohlkugelsegmentförmigen Abschnitt (9) gedrückt wird. Mit dem neuen Aufnahmeteil wird erreicht, dass zur Bevorratung lediglich noch Schrauben mit den verschiedenen Schraubenschäften bevorratet werden müssen, die dann zum Betrieb mit den einheitli-



#### **BENENNUNGEN VON "DE"**

Bis auf weiteres hat jede Benennung von "DE" in einer internationalen Anmeldung, deren internationaler Anmeldetag vor dem 3. Oktober 1990 liegt, Wirkung im Gebiet der Bundesrepublik Deutschland mit Ausnahme des Gebietes der früheren DDR.

#### LEDIGLICH ZUR INFORMATION

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- 1 -

# Aufnahmeteil für eine Pedikelschraube und Pedikelschraube

Die Erfindung betrifft ein Aufnahmeteil für eine Pedikelschraube zum gelenkigen Verbinden einer einen Gewindeschaftteil und einen kugelförmigen bzw. kugelsegmentförmigen Kopf aufweisenden Schraube mit einer Stange sowie eine Pedikelschraube zur Stabilisierung von Wirbelsäulensegmenten.

Aus der DE-AS 26 49 042 ist eine Pedikelschraube bekannt mit einem Gewindeteil und einem starr damit am kopfseitigen Ende vorgesehenen Aufnahmeteil. Es werden mehrere Paare solcher Schrauben jeweils in einem Abstand zueinander beidseitig von der Wirbelsäule in die Wirbelkörper eingeschraubt. Die jeweiligen Aufnahmeteile weisen Aufnahmeschlitze auf. Durch diese Aufnahmeschlitze der rechter bzw. linken Gruppe der Schrauben wird jeweils eine Gewindestange geführt. Mit Hilfe von Fixierungsschrauben wird die Stange dann am jeweiligen Auf-

nahmeteil fixiert. Ein Nachteil dieser Lösung besteht darin, daß es sehr schwierig ist, die Schrauben einerseits fest in die Wirbelkörper einzuschrauben und andererseits die Schrauben in zwei Ebenen gerade so zu stellen, daß die Achsen der Aufnahmeschlitze in den übereinander befindlichen Aufnahmeteilen so ausgerichtet sind, daß die Gewindestange ohne Verspannung der Schrauben durch die Aufnahmeschlitze hindurchführbar ist. Schon der Versuch erfordert sehr viel Zeit, was bei einer Operation an der Wirbelsäule ein großer Nachteil ist. Darüber hinaus läßt sich eine so genaue Ausrechnung fast nicht erreichen. Das Ergebnis ist, daß erhebiche Scherkräfte auf die Gewindestangen ausgeübt werden, was dazu führt, daß in der späteren Benutzung nach Abschluß der Operation die Stangen sogar abbrechen können.

Aus der EP O 242 708 A ist eine Pedikelschraube bekannt aus einer eigentlichen Schraube mit einem Gewindeschaftteil und einem kugelförmigen bzw. kugelsegmentförmigen Kopf und einem gelenkig damit verbindbaren Aufnahmeteil. Das Aufnahmeteil weist zwei durch einen Ring zusammengehaltene Kopfhälften auf, die auf ihren einander zugewandten Innenseiten hohlkugelsegmentförmige Abschnitte aufweisen, die den Kopf im zusammengesetzten Zustand so umfassen, daß dieser in der so gebildeten Hohlkugel um deren Mittelpunkt schwenkbar gehalten wird. Damit wird eine an sich sehr gut funktionierende Pedikelschraube geschaffen. Bei der Operation werden dann aber Schrauben verschiedenster Längen und ggf. auch verschiedenster Durchmesser benötigt. Bei der bisher bekannten Schraube ist es erforderlich, die kompletten Schrauben für die gewünschten Größen vorrätig zu halten. Wegen der erforderlichen hohen Präzision der beiden die kugelsegmentförmigen Abschnitte aufweisenden Schalenhälften und des diese zusammenhaltenden Ringes sind die Lagerkosten für solche kompletten Schrauben sehr hoch.

Aufgabe der Erfindung ist es, eine Möglichkeit zu schaffen, mit der die Kosten für die Vorratshaltung solcher Schrauben gesenkt werden.

Diese Aufgabe wird durch ein Aufnahmeteil nach Patentanspruch 1 gelöst.

Eine mit einem solchen Aufnahmeteil gebildete Pedikelschraube ist in Patentanspruch 2 gekennzeichnet.

Weiterbildungen der Erfindung sind in den Unteransprüchen gekennzeichnet.

Durch die Erfindung wird erreicht, daß zur Bevorratung nur die Schraubenschäfte mit unterschiedlicher Länge und unterschiedlicher Dicke, aber mit einheitlichem Kopf bevorratet werden. Die Lagerkosten werden dadurch erheblich gesenkt.

Weitere Merkmale und Zweckmäßigkeiten der Erfindung ergeben sich aus der Beschreibung eines Ausführungsbeispieles anhand der Figuren. Von den Figuren zeigen:

- Fig. 1 eine explosionsartige Seitenansicht der Pedikelschraube mit dem Aufnahmeteil, teilweise in geschnittener Darstellung, und
- Fig. 2 eine Schnittdarstellung durch das Aufnahmeteil mit eingesetzter Schraube und mit mit dem Aufnahmeteil verbundener Stange, in vergrößerter Darstellung.
- Fig. 3 eine gegenüber der in Fig. 1 um 90° um die Symetrieachse gedrehte Darstellung in vergrößertem Maßstab.

Die Pedikelschraube 1 weist eine eigentliche Schraube 2 mit Gewindeschaftteil 3 und einstückig damit ausgebildetem kugelsegmentförmigem Kopf 4 sowie den Aufnahmeteil 5 auf.

Der Aufnahmeteil 5 weist ein Gehäuse 6 zum Aufnehmen der Schraube 2 auf. Das Gehäuse weist im Inneren einen Aufnahmeraum 7 auf. Dieser ist in axialer Richtung des Aufnahmeraumes gesehen auf seinem einen Ende von einer Bohrung 8 begrenzt, deren Durchmesser kleiner ist als der zweifache Radius des kugelsegmentförmigen Abschnittes des Kopfes 4. Unmittelbar im Inneren an die Bohrung angrenzend ist ein hohlkugelsegmentförmiger Abschnitt 9 vorgesehen, dessen Radius im wesentlichen gleich dem Radius des kugelsegmentförmigen Abschnittes des Kopfes 4 ist. Der hohlkugelsegmentförmige Abschnitt 9 geht unmittelbar über in einen sich bis zu einer der Bohrung 8 gegenüberliegenden Öffnung 10 erstreckenden hohlzylindrischen Abschnitt 11, dessen Durchmesser gerade so wenig größer als der zweifache Radius des kugelsegmentförmigen Abschnittes des Kopfes 4 ist, daß der Kopf bei Einführen der Schraube 2 in den Aufnahmeteil in die in Fig. 2 gezeigte Position einführbar ist, in der der Kopf am hohlkugelsegmentförmigen Abschnitt 9 anliegt. Die Bohrung 8 ist, wie insbesondere aus Fig. 2 ersichtlich ist, koaxial zur Achse des zylinderförmigen Abschnittes ausgerichtet und weist von innen nach außen gesehen die Form eines Kegelabschnittes mit nach außen divergierender Wandung auf. Dadurch ist es möglich, die eingesetzte Schraube innerhalb eines durch den Durchmesser dieses Kegelabschnittes bestimmten Winkelbereiches um die Achse des hohlzylindrischen Abschnittes zu schwenken.

In einem Abstand von dem hohlkugelsegmentförmigen Abschnitt 9 weist das Gehäuse zwei um 180° gegeneinander versetzte und sich parallel zur Achse des hohlzylindrischen Abschnittes 11 erstreckende und zur Öffnung 10 hin offene Aufnahmeschlitze 12, 13 auf. Jeder der Aufnahmeschlitze weist wie bei der in der genannten EP 0 242 708 A beschriebenen Pedikelschraube auf der Außenseite jeweils eine Versenkunmg 14, 15 auf. Die Breite der Aufnahmeschlitze ist so gewählt, daß ein aufzunehmende Gewin-

destange 16 lose durch diese hindurchführbar ist. Wie am besten aus Fig. 1 ersichtlich ist, weist das Gehäuse ferner zwei um die Symetrieachse des Gehäuses um 90° gegen die Aufnahmeschlitze 12, 13 versetzte Schlitze 17 auf, die sich von der Öffnung 10 bis etwa zum inneren Rand des Aufnahmeraumes 7 erstrecken.

Ferner ist ein Druckelement 18 in Form eines zylinderförmigen Einsatzes vorgesehen. Der Außendurchmesser des Zylinders ist im wesentlichen gleich dem Innendurchmesser des hohlzylinderförmigen Abschnittes 11 und gerade um so viel kleiner gewählt, daß das Druckelement in dem Hohlzylinder verschiebbar ist. Wie am besten aus Fig. 1 ersichtlich ist, ist das Druckelement bevorzugt als Hohlzylinder ausgebildet. Das beim Einsetzen in das Gehäuse 6 dem hohlkugelsegmentförmigen Abschnitt zugewandte Ende weist einen ebenfalls hohlkugelsegmentförmigen Abschnitt 19 auf. Der Radius der Krümmung ist im wesentlichen gleich dem Radius der Krümmung des hohlkugelsegmentförmigen Abschnittes 9 und im wesentlichen gleich dem Radius des kugelsegmentförmigen Abschnittes 4 gewählt.

Das Druckelement 18 weist ferner zwei den Aufnahmeschlitzen 12, 13 entsprechende Aufnahmeschlitze 20, 21 auf, die sich in einem Abstand von dem hohlkugelsegmentförmigen Abschnitt 19 parallel zur Symetrieachse des Druckelementes und bis zu der gegenüberliegenden Öffnung 22 des Druckelementes erstrecken und die zur Aufnahme der Gewindestange 16 bestimmt sind. Ferner sind wiederum im wesentlichen um 90° um die Symetrieachse gegen die Aufnahmeschlitze versetzt zwei gegenüberliegende Schlitze 23 vorgesehen, die unmittelbar oberhalb des hohlkugelsegmentförmigen Abschnittes 19 beginnen und auf der gegenüberliegenden Seite offen sind.

Ferner sind Muttern 24, 25 vorgesehen, die dazu dienen, in der in Fig. 2 gezeigten Weise die Stange 16 mit der Pedikelschraube zu verbinden.

Grundsätzlich ist es möglich, den Kopf 4 auf seiner dem Gewindeschaftteil 3 abgewandten Seite kugelförmig auszubilden. Die Aufnahmeschlitze und die Versenkungen in dem Gehäuse 6 sind dann so zu wählen, daß die Stange 16 in einem ausreichenden Abstand über dem Kopf liegt, damit dieser beim Verschwenken der Schraube nicht mit der Stange bzw. den diese haltenden Schrauben in Kontakt gelangt. Bevorzugt weist der Kopf auf seinem dem Gewindeschaftteil 3 abgewandten Ende eine sich senkrecht zur Schraubenachse erstreckende ebene Fläche 26 auf. In diese ist eine Vertiefung eingelassen, in die mit einem Schraubendreher Werkzeug zum Drehen der Schraube eingegriffen werden kann.

Vor dem Einsetzen der Pedikelschraube wird zunächst die Schraube 2 mit gewünschtem Schaftdurchmesser und gewünschter Schaftlänge in die in Fig. 2 gezeigte Position so eingesetzt, daß der Kopf mit seinem kugelsegmentförmigen Teil in dem hohlkugelsegmentförmigen Abschnitt ruht. Dann wird die Schraube in den jeweiligen Wirbelkörper eingeschraubt, in dem mit dem zugehörigen Werkzeug in die dafür vorgesehene Vertiefung des Kopfes 4 eingegriffen wird. Nach dem Einschrauben (gewünschtenfalls auch vorher) wird das Druckelement in der am besten aus Fig. 2 ersichtlichen Weise so in den hohlzylinderförmigen Abschnitt 11 eingesetzt, daß sein hohlkugelsegmentförmiger Abschnitt 19 auf dem sphärischen Bereich des Kopfes 4 ruht. Die Aufnahmeschlitze von Gehäuse 6 und Druckelement 18 werden parallel zueinander ausgerichtet. Dann wird die damit zu verbindende Stange 16 in die Aufnahmeschlitze eingelegt und durch Anziehen der Muttern 24 und 25 fest damit verbunden. Der Grund der Aufnahmeschlitze 20, 21 ist um so viel zum freien Ende der Schlitze hin versetzt, daß beim Verschrauben mit den die Stange haltenden

Muttern eine zusätzliche Schubkraft in Richtung zu dem hohlkugelsegmentförmigen Abschnitt hin auf den Kopf 4 wirkt. Durch
die Schlitze 17 und 23 ist ein geringes Nachgeben der Zylinderwandung des Gehäuses 6 dahingehend möglich, daß eine noch stärkere Klemmkraft auf den Kopf wirkt. Durch das Vorsehen des
Druckelementes 18 wird erreicht, daß bei diesem für den Halt
erforderlichen Zusammendrücken der Kopf nicht etwa von dem
innigen Kontakt mit dem hohkugelsegmentförmigen Abschnitt 19 in
das Innere hineingedrückt, sondern vollständig von einem hohlkugelförmigen Bereich umgeben von dem Druckelement sogar in
Richtung des hohlkugelsegmentförmigen Abschnittes 19 gedrückt
wird. Dadurch wird eine feste Arretierung in der eingestellten
Winkelposition erreicht.

- 8 -

#### PATENTANSPRÜCHE

1. Aufnahmeteil für eine Fedikelschraube zum gelenkigen Verbinden einer einen Gewindeschaftteil (3) und einen kugelförmigen bzw. kugelsegmentförmigen Kopf (4) aufweisenden Schraube (2) mit einer Stange (16),

mit einem Aufnahmeraum (7) im Inneren, der an seinem einen Ende eine Bohrung (8) zum Hindurchführen des Gewindeschaftteiles (3) angrenzend an diese innen einen hohlkugelsegmentförmigen Abschnitt (9) zum Anliegen des Kopfes (4) der aufzunehmenden Schraube (2) und auf der der Bohrung gegenüberliegenden Seite eine Öffnung (10) zum Einführen der Schraube (2) aufweist, und mit einem Druckelement (18), welches in zusammengesetztem Zustand eine Kraft so auf den Kopf ausübt, daß dieser gegen den hohlkugelsegmentförmigen Abschnitt (9) gedrückt wird.

2. Pedikelschraube (1) zur Stabilisierung von Wirbelsäulensegmenten,

mit einem Gewindeschaftteil (3.) und einem damit gelenkig verbundenen kopfseitigen Aufnahmeteil (5) für eine Stange (16), einem kugelförmigen bzw. kugelsegmentförmigen Kopf (4) am Ende des Gewindeschaftteiles,

einem Aufnahmeraum (7) in dem Aufnahmeteil (5), der an seinem einen Ende eine Bohrung (8) zum Hindurchführen des Gewindeschaftteiles (3) angrenzend an diese innen einen hohlkugelsegmentförmigen Abschnitt (9) zum Anliegen des Kopfes (4) und auf der der Bohrung gegenüberliegenden Seite eine Öffnung (10) zum Einführen des Gewindeschaftteiles (3) mit Kopf (4) aufweist, und

mit einem Druckelement (18), welches in zusammengesetztem Zustand eine Kraft so auf den Kopf ausübt, daß dieser gegen den hohlkugelsegmentförmigen Abschnitt (9) gedrückt wird.

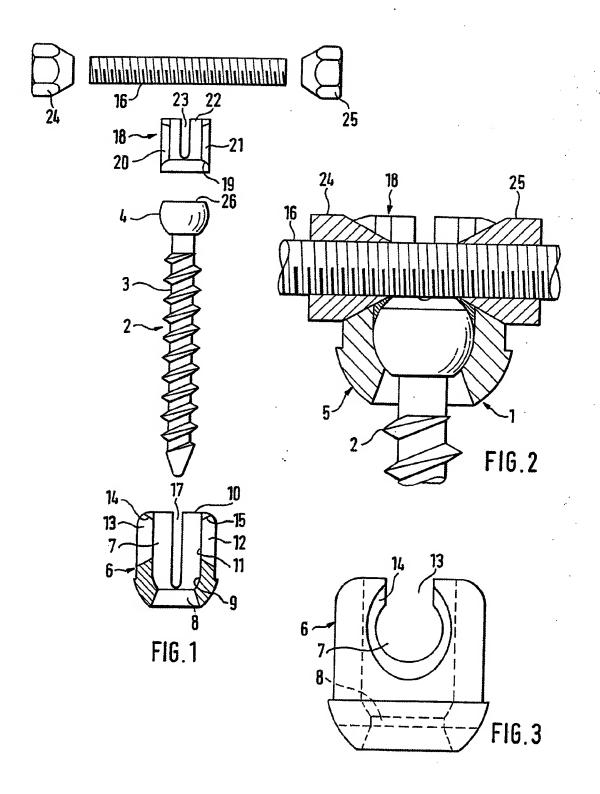
- 3. Element nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß das Aufnahmeteil (5) an seinem der Bohrung (8) abgewandten Abschnitt wenigstens einen sich bis zum offenen Rand hin erstreckenden Schlitz (17) und winkelmäßig gegen diesen versetzt zwei einander gegenüberliegende Schlitze (12, 13) zum Hindurchführen der Stange (16) und Arretieren derselben mittels Muttern (24, 25) aufweist.
- 4. Element nach Anspruch 1 oder 3, dadurch gekennzeichnet, daß das Druckelement (18) auf seinem dem Kopf (4) zugewandten Ende einen zu dem Kopf hin gerichteten hohlkugelsegmentförmigen Abschnitt (19) aufweist.
- 5. Element nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Radien der von hohlkugelsegmentförmigen Abschnitten (9, 19) und Kugel bzw. Kugelsegment (4) im wesentlichen gleich sind.
- 6. Element nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß der Aufnahmeraum (7) in seinem der Bohrung (8) gegenüberliegenden Abschnitt angrenzend an den hohlkugelsegmentförmigen Abschnitt (9) hohlzylindrisch ausgebildet ist.
- 7. Element nach Anspruch 6, dadurch gekennzeichnet, daß das Druckelement (18) einen zylinderförmigen Abschnitt aufweist, dessen Außendurchmesser im wesentlichen gleich dem Innendurchmesser des hohlzylindrischen Abschnittes (11) ist.
- 8. Element nach einem der Ansprüche 3 bis 7, dadurch gekennzeichnet, daß das Druckelement (18) zwei den Schlitzen zum Aufnehmen entsprechende Schlitze (20, 21) aufweist, deren Grund sich soweit von dem mit dem Kopf in Ein-

griff bringbaren Rand weg erstreckt, daß beim Verschrauben mit den die Stange haltenden Muttern eine zusätzliche Schubkraft in Richtung zu dem hohlkugelsegmentförmigen Abschnitt hin auf den Kopf wirkt.

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#### INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 90/01184

	IFICATION OF SUBJECT MATTER (If several classif		30/01104
	to international Patent Classification (IPC) or to both Nati	onal Classification and IPC	
Int.	.CI. <sup>5</sup> A 61 B 17/58	•	
II. FIELDS	SEARCHED		
	Minimum Documen	tation Searched 7	
Classification	on System (	Classification Symbols	
Int.	CI. <sup>5</sup> A 61 B		
	Documentation Searched other to the Extent that such Documents	han Minimum Documentation are included in the Fields Searched •	
		-	
III. DOCU	MENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of Document, 11 with indication, where app	ropriate, of the relevant passages 12	Relevant to Claim No. 13
X	EP, A, 0242708 (J.HARMS & L. 1987, see the whole docu		1-8
А	US, A, 4805602 (R.M. PUNO & 1989, see column 4, line 57; figures 4-5	1-2	
A	DE, A, 3711013 (J. HARMS & L 1988, see figure 1	1-2	
"A" doc con "E" eari filin "L" doc whis cita "O" doc oth "P" doc late	al extegories of cited documents: 10  cument defining the general state of the art which is not sidered to be of particular relevance.  Iter document but published on or after the international grate  cument which may throw doubts on priority claim(s) or  ch is cited to establish the publication date of another  tion or other special reason (as specified)  cument referring to an oral disclosure, use, exhibition or  or means  cument published prior to the international filling date but  ir than the priority date claimed	"T" later document published after the principle of the understand the principle invention."  "X" document of particular relevant cannot be considered novel or involve an inventive step.  "Y" document of particular relevant cannot be considered to involve document is combined with one ments, such combination being of in the art.  "&" document member of the same principle."	ct with the application but or theory underlying the ce; the claimed invention cannot be considered to ce; the claimed invention or inventiva step when the or more other such docu-
	Actual Completion of the international Search	Date of Mailing of this International Se	arch Report
	ovember 1990 (15.11.90)	5 December 1990 (05	.12.90)
internation	al Searching Authority	Signature of Authorized Officer	
Euro	pean Patent Office		

## ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

EP 9001184 SA 39036

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 26/11/90

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Patent document cited in search report	Publication date	Patent family member(s)		Publication date	
EP-A- 0242708	28-10-87	DE-C- JP-A- US-A-		22-10-87 02-12-87 07-08-90	
US-A- 4805602	21-02-89	None	5 <b>3 3 5 5 5 5</b> 5 5 5 5 5 5 5 5 5 5 5 5 5 5	******	
DE-A- 3711013	09-06-88	None		*******	
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#### INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen PCT/EP 90/01184

I. KLASSIFIKATION DES ANMELDUNGSGEGENSTANDS (bei mehreren Klassifikationssymbolen sind alle anzugeben) <sup>8</sup>						
		onalen Patentklassifikation (IPC) oder nach der	nationalen Klassifikation und der IPC	·		
Int.C	13 A 61	L B 17/58	· · · · · · · · · · · · · · · · · · ·	·		
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Recherchierte nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Sachgebiste fallen <sup>8</sup>						
IILEINS	CHLÄGIGE	VERÖFFENTLICHUNGEN <sup>9</sup>				
Art*	Kennzeich	nnung der Veröffentlichung <sup>11</sup> ,soweit erforderlich	unter Arigabe der maßgeblichen Teile <sup>12</sup>	Betr. Anspruch Nr. 13		
х	EP,	1-8				
A	US,	1-2				
A		DE, A, 3711013 (J. HARMS & L. BIEDERMANN) 9. Juni 1988 siehe Figur 1				
Besonders Kategorien von angegebenen Veröffentlichungen.     "A" Veröffentlichung, die den allgemeinen Stand der Technik "T" Spätere Veröffentlichung, die nach dem Internationalen A						
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"L" Veröffentlichung, die gesignet ist, einen Prioritätsenspruch zweifelhaft erscheinen zu lassen, oder durch die das Veröffentlichung von besonderer E fentlichungsdatum einer anderen im Recherchenbericht genammen Veröffentlichung belegt werden soll oder die aus einem			"X" Veröffentlichung von besonderer Bede te Erfindung kann nicht als neu oder a	utung; die beanspruch-		
anderen besonderen Grund angegeben ist (wie ausgeführt) "Y" "O" Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Banutzung, eine Ausstellung oder andere Maßnahmen			"Y" Veröffentlichung von besonderer Bede te Erfindung kann nicht als auf erfin ruhend betrachtet werden, wenn die einer oder mehreren anderen Veröffen	derischer Tätigkeit be- Veröffentlichung mit Bichungen dieser Kata-		
gorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheilegend ist um, aber nach dem beenspruchten Prioritätsdatum veröffentlicht worden ist						
IV. BESCHEINIGUNG						
Datu	m des Abschlu	sses der internationalen Recherche	Absendedatum des Internationalen Rechen			
15. November 1990 - 5 EEC 1990						
inten	nationale Reci	nerchenbehörde	Unterschrift des bevollmächtigten Bediens	tetels		
Europäisches Patentamt			sore to sale	C/W/1616		

#### ANHANG ZUM INTERNATIONALEN RECHERCHENBERICHT ÜBER DIE INTERNATIONALE PATENTANMELDUNG NR.

EP 9001184 SA 39036

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten internationalen Recherchenbericht angeführten Patentdokumente angegeben.
Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am 26/11/90 Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung	
EP-A- 0242708	28-10-87	DE-C- JP-A- US-A-	3614101 62277954 4946458	22-10-87 02-12-87 07-08-90	
US-A- 4805602	21-02-89	Keine			
DE-A- 3711013	09-06-88	Keine			
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#### PCT

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FR

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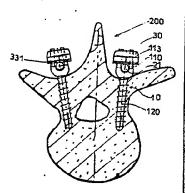
#### Publiée

Avec rapport de recherche internationale.

(54) Title: DEVICE FOR STRAIGHTENING, SECURING, COMPRESSING AND ELONGATING THE SPINAL CO-LUMN

(54) Titre: DISPOSITIF DE REDRESSEMENT, FIXATION, COMPRESSION, ELONGATION DU RACHIS

The invention relates to a process and device for securing, elongating and compressing a spinal column, of simple design, which is easy and precise in use, leaving no projecting part. The process of the invention for straightening and supporting a spinal column consists in securing screwed implants (10) or hooks on either side of the curvature of the spine and interlinking them by at least two rods (20, 21) designed to act as struts; said rods (20, 21) are introduced longitudinally into grooves (113) perpendicular to the screw (120) fitted in the body (110) of the implants (10) or hooks and then fixed in the base of the grooves (113) by crimping resulting from the deformation of the sides of the groove (113) by the closing of its sides; said deformation is obtained via a conicallythreaded nut (30) and a cylindrical male thread cut around the body (110) of the implants (10). Application: straightening and supporting the spinal column in the event of scoliosis or fracture, for example.



#### (57) Abrégé

L'invention concerne un procédé et un dispositif pour la fixation, l'élongation et la compression d'un rachis, de conception aisée et d'utilisation simple et précise, ne laissant subsister aucune partie saillante. Le procédé de redressement et d'étaiement d'un rachis de l'invention consiste à fixer des implants vissés (10) ou crochets, de chaque côté de la courbure du rachis, à relier ceux-ci par au moins deux tiges (20, 21) destinées à servir d'étais; les dites tiges (20, 21) sont introduites longitudinalement dans des rainures (113) perpendiculaires à la vis (120), prévues à cet effet dans le corps (110) des implants (10) ou crochets, puis bloquées dans le fond des rainures (113), par sertissage résultant de la déformation par rapprochement des côtés de la rainure (113); la déformation par rapprochement des côtés de la rainure (113) est obtenue par l'intermédiaire d'un écrou à filetage conique (30) et d'un filetage cylindrique mâle réalisé autour du corps (110) des implants (10). Application: redressement et étaiement du rachis en cas de scoliose ou de fracture, par exemple.

#### **DESIGNATIONS DE "DE"**

Jusqu'à nœuvel avis, toute désignation de "DE" dans toute demande internationale dont la date de dépôt international est antérieure au 3 octobre 1990 a effet dans le territoire de la République fédérale d'Allemagne à l'exception du territoire de l'ancienne République démocratique allemande.

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# <u>Dispositif de redressement, fixation, compres-</u> <u>sion, élongation du rachis.</u>

L'invention concerne un dispositif pour le redressement et l'étaiement d'un rachis présentant une déviation anormale.

- Le redressement et l'étaiement d'un rachis sont deux opérations nécessaires en cas de fracture de vertèbres, ou en cas de déviation de la colonne vertébrale résultant, par exemple, d'une scollose ou d'une cyphose.
- Les dispositifs connus de redressement et d'étalement des rachis ont fait l'objet, depuis un certain nombre d'années de diverses réalisations. L'un des plus connus est celui universellement utilisé, dit de "HARRINGTON" dont nous ferons une brève description, dans ce qui suit, étant donné son éloignement relatif par rapport à l'invention.

Ce dispositif suscité comprend un système d'élongation et un système de compression, disposés respectivement sur la concavité et la convexité de la courbure du rachis ; le système d'élongation est constitué principalement d'une tige métallique cylindrique sur laquelle coulissent et peuvent être solidarisés de manière amovible deux éléments d'ancrage dits inférieur et supérieur ; l'élément inférieur est accroché sur la lame de la vertèbre extrême inférieure de la courbure et le crochet supérieur est disposé sous l'apophyse articulaire de la vertèbre extrême supérieure de la courbure ; l'une des extrémités de la tige est crantée de manière à permettre le réglage de l'écartement relatif des deux éléments d'ancrage, et à fixer la valeur de cet 30 écartement par l'intermédiaire d'un clip de blocage ; le système de compression comporte une tige filetée sur laquelle coulissent des éléments d'ancrage, dont la position sur la tige peut être fixée par des écrous exerçant une

pression sur les éléments et sur les vertèbres.

Une telle technique présente un certain nombre d'inconvénients tenant principalement au manque de précision du ré5 glage de l'ouverture de la courbure due à la présence des
crans, au fait que l'appui est localisé au niveau des deux
seules vertèbres extrêmes de la courbure et que les crochets peuvent tourner autour de la tige métallique, aucune
action de recentrage vers l'axe du tronc n'étant exercée,
10 ni de dérotation des vertèbres du sommet, et au fait que la
tige présente des risques de rupture.

La plupart de ces inconvénients ont été résolus par la création de dispositifs conduisant à la mise en place d'éléments d'ancrage sur un certain nombre de vertèbres de la courbure; ces éléments sont constitués d'une partie réalisant l'ancrage, vis ou crochet, et d'un corps de fixation à la tige d'étaiement.

- 20 Il existe actuellement trois catégories de réalisation différentes des corps de fixation, à savoir les corps fermés, les corps ouverts latéralement et les corps ouverts longitudinalement.
- 25 Les premiers nécessitent le passage de la tige axialement dans le corps de fixation ; le blocage de la tige en rotation et en translation étant obtenu au moyen de petites vis introduites transversalement à la tige, dans un orifice du corps de fixation.

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Or, le passage de ces tiges axialement dans le corps, après les avoir recourbées est une opération très contraignante et longue; en outre, elle nécessite de procéder au hochement des corps de fixation des éléments d'ancrage dans lesquels la tige est déjà insérée; ce qui provoque le dévissage des petites vis de pression assurant le blocage de ladite tige ; au surplus, ces petites vis mettent en évidence des parties saillantes, même lorsque celles-ci sont brisées à la fin de l'intervention, et pouvant être à l'origine de blessures et de lésions.

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D'autres dispositifs remédient à certains de ces inconvénients en prévoyant des corps de fixation à ouverture la térale ; mais ils nécessitent toujours l'utilisation de vis de pression pour bloquer la tige.

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Alors que d'autres dispositifs prévoient des corps de fixation à ouverture longitudinale tel que celui décrit dans le brevet suivant :

15 -Brevet européen 0 128 058, ayant pour objet un dispositif d'étalement et de redressement du rachis dont le corps de fixation présente une ouverture longitudinale; le blacage de la tige dans le corps étant obtenu par l'intermédiaire d'éléments complémentaires, dits bloqueurs, constitués de petits anneaux cylindro-coniques, surmontés d'un corps rectangulaire, le tout étant percé d'un trou taraudé destiné au vissage d'une vis de pression; l'introduction de cet élément dans le corps de fixation, et le vissage de la vis de pression assurant la solidarisation axiale et radiale de la tige au corps de fixation.

Ces dispositifs sont de conception onéreuse, compte-tenu du nombre important de pièces mises en oeuvre ; en outre, ils n'éliminent pas les parties saillantes dues à la pré-30 sence des vis ; ces éléments complémentaires devant en outre être placés sur la tige préalablement, nécessitent une orientation particulière des implants;

Un autre dispositif combinant la possibilité d'introduc-35 tion longitudinale des tiges et assurant un blocage de celles-ci par un nombre plus réduit de pièces, a été décrit dans la demande de brevet suivante :

demande de brevet français 2 624 720 : dans laquelle le corps de fixation présente une ouverture longitudinale formant une rainure, fermée au moyen d'un capuchon vissé autour de la partie extérieure de la rainure ; le blocage définitif étant réalisé par l'intermédiaire d'une vis pointeau introduite dans un bossage du capuchon ; ce dispositif ne permet pas l'élimination des parties saillantes ;
10 en outre la pression exercée sur la tige pour son blocage ne s'effectue que, d'une part au contact de deux bords opposés du capuchon, et, d'autre part, au niveau de la génératrice d'intersection entre la tige et le fond de la rainure, ce qui ne peut conduire à un blocage parfait ; bien que le blocage réalisé dans ce cas soit supérieur à celui réalisé par les dispositifs précédemment décrits.

La présente invention a pour but de remédier à ces inconvénients et se propose de résoudre le problème consistant à 20 créer un dispositif d'étalement et de redressement de conception simple et peu onéreuse, assurant une bonne fixation des implants sur les tiges à fonction d'étal, renforçant ainsi la solidité de l'ensemble; sa mise en place étant rapide et précise et ne laissant subsister aucune 25 partie saillante.

Le dispositif de redressement et d'étalement d'un rachis, constitué d'implants vissés ou de crochets reliés par au moins deux tiges solidarisées entre elles par l'intermé30 diaire d'éléments de raccordement et de liaison; lesdites tiges étant introduites dans des rainures perpendiculaires à la vis, prévues à cet effet dans le corps des implants ou des crochets puis bloquées dans le fond des rainures, se caractérise en ce que le blocage des tiges dans le fond des rainures aménagées dans le corps des implants ou des crochets, est obtenu sous l'effet d'une déformation par

rapprochement des côtés de la rainure par l'intermédiaire d'un système à vis cylindrique et à écrou à filetage conique, dans lèquel, la solidarisation des tiges par rapport à la traverse filetée est obtenue par l'intermédiaire de 5 quatre mors dont l'un est fixé à l'une des extrémités de la traverse filetée et dont la position des trois autres sur la traverse est réglable par l'intermédiaire d'un écrou maintenu dans une cage, dont la rotation s'obtient par l'intermédiaire d'un système roue et vis sans fin ; la fi-10 xation des vis des implants s'obtient par l'intermédiaire d'un filet triangulaire à 45°, dont l'un des câtés, situé en arrière par rapport à la pointe de la vis, forme un angle droit par rapport à la tige de la vis ; les éléments de raccordement longitudinaux de tronçons de tiges sont consti-15 tués d'une plaquette moletée dont les extrémités comportent chacune un orifice cylindrique de passage du corps de tête d'implants séparée ou non de sa vis sur laquelle se monte un écrou à filetage conique . Les éléments de liaison latéraux des tiges sont constitués d'une plaquette compor-20 tant un orifice de passage du corps de la tête d'un implant séparée ou non de sa tige, et une rainure de même largeur permettant elle aussi, le passage du corps de la tête d'un implant et d'écrous assurant le blocage en position de l'ensemble ; la tige filetée de rappel de deux crachets 25 l'un vers l'autre est montée dans les orifices filetés de même pas, percés dans le corps desdits crochets.

Le système à vis cylindrique et à écrou conique, assurant le rapprochement des côtés du corps des implants ou des crochets, est constitué d'un filetage cylindrique mâle, réalisé autour du corps des implants ou des crochets sur une longueur un peu inférieure à la profondeur de la rainure et d'un alésage conique fileté de même pas, réalisé dans l'axe de l'écrou; le diamètre de la base de l'alésage conique fileté de l'écrou correspond au diamètre du filetage cylindrique mâle réalisé autour du corps des implants

ou des crochets; la hauteur de l'écrou correspond approximativement à la distance séparant l'entrée de la rainure de la tige, lorsque cette dernière est en place dans le fond de la dite rainure.

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Suivant une forme particulière de réalisation de l'invention, la base de l'écrou comporte des dents disposées obliquement; la section desdites dents a la forme d'un triangle rectangle dont la base est confondue avec celle de 10 l'écrou et dont l'hypoténuse est dirigée dans le sens de rotation donné à l'écrou pour obtenir le vissage et le serrage de celui-ci.

Les dents disposées obliquement, peuvent être striées se-15 lon des cercles concentriques à l'axe de l'écrou.

Suivant une autre forme de réalisation de l'invention, les tiges servant d'étais sont filetées sur toute leur longueur, et le fond de la rainure, réalisée dans le corps des 20 implants ou des crochets, comporte une empreinte demi-cylindrique dont le relief correspond à celui du filetage réalisé sur les tiges étais.

Les implants sont réalisés en titane pur, ou en alliage de 25 titane implantable, par exemple en Ti Al6 V4.

La vis sans fin d'entraînement de la roue de manoeuvre de l'écrou, assurant le déplacement des mors mobiles, sur la traverse filetée, comporte une empreinte permettant sa manoeuvre par l'intermédiaire d'un tournevis ou d'une clé.

Le moyen de manoeuvre en rotation de la tige filetée de rappel des crochets deux à deux peut être constitué d'une em-35 preinte permettant sa manoeuvre par l'intermédiaire d'un tournevis ou d'une clé.

Les avantages procurés par l'invention tiennent essentiellement en ceci que d'une part, le dispositif d'étaiement et.de redressement du rachis ne laisse subsister au-5 cune partíe saillante, une fois mis en place, ceci étant obtenu grâce au blocage de la tige au moyen d'un écrou à tête arrondie et à alésage conique, ce qui élimine la nécessité d'utiliser des vis de pression ; d'autre part en ce que le blocage réalisé est optimum du fait que la pression 10 exercée pour l'obtention du blocage est réalisée sur une surface d'appui importante de la tige ; ce blocage étant accru par la présence d'une denture sur la base de l'écrou coopérant avec des aspérités ménagées sur les tiges, ou d'une empreinte au fond de la rainure coopérant avec un fi-15 letage ménagé sur toute la longueur de la tige d'étaiement; le dispositif étant en outre de conception et d'utilisation simples, rapides et précises.

D'autres caractéristiques et avantages apparaîtront dans 20 la description qui va suivre, de plusieurs formes de réalisation de l'invention, données à titre d'exemples non limitatifs, au regard des figures des planches annexées dans lesquelles :

- 25 -La figure 1 représente une vue en élévation longitudinale d'un implant à vis et une vue en élévation latérale d'un écrou, représentant, deux éléments constitutifs d'une forme particulière de réalisation de l'invention.
- 30 -La figure 2 est une représentation partielle de la vis, montrant son filet triangulaire.

-La figure 3 représente deux vues en élévation longitudinale de deux tiges à fonction d'étai, utilisées dans deux 35 formes différentes de réalisation de l'invention. -La figure 4 représente une vue en élévation latérale de l'écrou, utilisé dans la seconde forme de réalisation de l'invention.

5 -La figure 5 est une vue en plan de dessous, du même écrou, correspondant à une troisième forme de réalisation de l'invention.

-La figure 5 est une vue en coupe partielle suivant A-A de 0 la figure précédente.

-La figure 7 représente une vue de dessus d'une vertèbre, le dispositif d'étaiement et de redressement de l'invention étant en place.

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-La figure 8 représente une vue de dessus d'une forme de réalisation su dispositif de raccordement de deux tiges d'étaiement, disposées de part et d'autre d'un rachis, assurant leurs tension et écartement relatifs.

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-La figure 9 est une vue de l'arrière du même dispositif présentant une coupe.

-La figure 10 est une vue dans un plan sagittal, du disposi-25 tif d'étaiement de l'invention mis en place.

-Les figures 11,12,13 et 14 représentent des vues en élévation longitudinale, de différentes formes de réalisation d'un crochet conforme à l'invention.

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-Les figures 11a, 12a, 13a, et 14a en sont respectivement des vues de dessus, et la figure 13b est une vue de côté de la troisième forme de réalisation du crochet décrit.

35 - La figure 15 représente schématiquement une pince utilisée dans l'invention pour la manipulation des crochets.

-la figure 16 est une vue de côté partielle de la pince.

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- la figure 17 représente, à travers trois vues, une agrafe utilisée dans l'invention.
- -la figure 18 représente une vue partielle, dans un plan 10 frontal, du dispositif de compression de deux vertèbres, conforme à l'invention.
  - la figure 19 est une vue de côté du dispositif de compression de deux vertèbres.

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- la figure 20 représente une vue de côté d'un dispositif de connexion longitudinale de tronçons de tiges.
- la figure 21 représente une vue de côté d'un dispositif de 20 liaison latérale de tiges,
  - la figure 22 représente une vue de dessus d'un dispositif de liaison latérale de tiges,

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En se référant à la figure 1, on observe deux éléments constitutifs d'une forme particulière de réalisation de l'invention, à savoir un implant 10 et un écrou 30 ; dans cette forme de réalisation l'implant 10 prend la forme générale d'une vis dont la tête est formée d'un corps 110 présentant une rainure 113 ménagée dans le plan de la vis 120 de l'implant 10, débouchant à la partie postérieure du corps 110 de l'implant 10 ; et délimitée par deux côtés parallèles 111,112 dudit implant 10, un filetage 114 est réalisé autour du corps 110, sur les trois quarts environ de la longueur de la rainure 113 et est destiné à recevoir le file-

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tage de l'alésage 310 de l'écrou 30.

Lors de la mise en place du dispositif d'étaiement de l'invention, une tige à fonction d'étai est introduite, de cha-5 que côté du rachis, successivement dans les rainures 113 de chaque comps 110 d'implants 10 ; ces derniers étant préalablement vissés dans les vertèbres situées entre les deux vertèbres extrêmes de la courbure d'un rachis, ou de part et d'autre d'une vertèbre fracturée, selon le cas ; puis la 10 tige est bloquée au fond de la rainure 113 de chaque implant 10, par pression exercée sur celle-ci ; le fond de chaque rainure 113 est formé d'une partie semi-circulaire d'un diamètre correspondant à celui de la tige ; la pression exercée est réalisée lors du vissage de l'écrou 30 autour 15 du corps 110 de l'implant 10, par le rapprochement des deux côtés 111,112 de l'implant 10 délimitant la rainure 113, l'un par rapport à l'autre de manière à enserrer la tige et à la bloquer au fond de la rainure 113 ; ce rapprochement est réalisable grâce au choix d'un écrou 30 à alésage conique 310, le rapprochement obtenu des deux côtés 111,112 étant proportionnel à la quantité de surface de l'alésage 310, vissée autour du corps 110 à de l'implant 10 ; le diamètre de la base 311 de l'alésage 310 de l'écrou 30 correspondant à celui du filetage cylindrique mâle 114 des implants 10.

Or, si ces moyens sus-décrits sont suffisants pour obtenir un blocage correct de la tige par rapport à l'implant 10, d'autres moyens ont été prévus pour renforcer ce blocage, de manière à augmenter la sécurité d'utilisation du dispositif de l'invention; ces moyens sont la présence d'une empreinte demi-cylindrique 115 réalisée dans le fond de chaque rainure 113, dont le relief, en l'espèce un filetage en demi-lune est d'une forme lui permettant de coopérer avec le même relief réalisé sur toute la longueur des tiges d'étaiement; ainsi la disposition de la tige au fond de la

rainure 113 permettra d'obtenir la solidarisation axiale de la tige par rapport au corps 110 de l'implant 10, après le vissage de l'écrou 30 sur la totalité de sa hauteur ; la pression sera en outre exercée sur la tige par, d'une part, deux bords opposés de l'écrou 30, et, d'autre part, par les côtés de la rainure 113 sur au moins la moitié de la périphérie de la tige.

On pourra remarquer que la tête 33 de l'écrou 30 présente des bords arrondis et sa face extérieure opposée à la base 32, se situe lorsque l'écrou 30 est en place, dans le plan de l'extrémité des côtés 111,112 de la rainure 113 ; en outre, les parties latérales de l'écrou 30 se retrouvent dans le prolongement des côtés non déformés du corps 110 de 1'implant 10, de manière à ce que l'ensemble implant 10, écrou 30, ne présente plus aucune partie saillante.

Sur la figure 2, on remarque que la vis 120 reliée au corps de l'implant présente un filet triangulaire 121 formant un angle de 45°, la vis 120 peut dans certains cas d'utilisation, être autotaraudeuse ; on notera que l'un des côtés 122, situé en arrière par rapport à la pointe de la vis 120, forme un angle droit par rapport à la tige de l'implant.

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Sur la figure 3, on peut observer deux tiges 20,21 d'étaiement correspondant à celles utilisées dans les deux formes de réalisation différentes énoncées ci-dessus; la première 20 (fig.3.a) est filetée sur toute sa longueur, de manière à coopérer avec le relief du fond de la rainure des implants; la seconde 21 (fig.3b) présente des aspérités telles que celles pouvant résulter d'un moletage ou d'un guillochage, et pourra être utilisée dans la première forme de réalisation décrite, bien que l'utilisation, dans ce cas, d'une tige à surface lisse soit aussi possible; mais cette seconde tige 21 est plus particulièrement des-

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tinée à être utilisée dans une troisième forme de réalisation du dispositif de l'invention que l'on va décrire dans ce qui sult.

5 Sur les figures 4,5 et 6, l'écrou 30 est pourvu à sa base 32 d'une série de dents 331 destinées à coopérer avec les aspérités de la surface de la tige d'étaiement, de manière à ce qu'un glissement de l'écrou 30 par rapport à la surface de la tige soit obtenu lors du serrage final de celui-ci autour du corps de l'implant, et au contraire, à ce qu'un blocage de la tige soit obtenu par insertion des dents 331 dans les orifices des aspérités, lors d'un dévissage involontaire de l'écrou 30.

15 Ces dents 331 peuvent être disposées radialement, mais sont dans cette forme particulière de réalisation décrite, disposées de façon à être légèrement inclinées par rapport aux rayons de la base 311 de l'alésage 310 de l'écrou 30 ; cette particularité permet qu'un certain nombre de dents 331 soient toujours engagées dans les aspérités, lors du dévissage, ou en position de blocage ; ce qui n'est pas obtenu lorsque les dents 331 sont disposées radialement ; afin d'obtenir un renforcement du blocage de l'écrou 30, on a également prévu une strie circulaire 332.

Sur la figure 7, on peut observer une vertèbre 200 dans laquelle sont vissés deux implants 10 à vis 120 ; la tige d'étaiement 21 ayant été mises en place dans les rainures 113 du corps 110 des implants 10 et solidarisées à ces derniers par l'intermédiaire d'un écrou 30 vissé autour du corps 110, dont la base est pouvue de dents 331, conforme à la dernière forme de réalisation décrite ; cette figure nous permet de considérer les surfaces d'appui par l'intermédiaire desquelles la pression de blocage est exercée sur la tige 21 ; lesquelles se trouvent d'une part au niveau de la base de l'écrou 30, d'autre part au niveau

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du fond de la rainure 113, sur un peu plus de la demi-périphérie de la tige 21.

En se reportant aux figures 8 et 9, on peut observer une forme particulière de réalisation du dispositif de raccordement des deux tiges 20 et 21, mises en place de chaque côté d'un rachis.

Ce dispositif est constitué d'une traverse filetée 40 sur 10 l'une des extrémités 41 de laquelle a été fixé un premier mors 50 ayant la forme générale d'un crochet, trois autres mors 51,52,53 pouvant se déplacer longitudinalement sur la traverse 40, par l'intermédiaire d'un écrou 60 maintenu dans une cage 531, solidaire du mors mobile 51,52,53 et enture hélicoïdale 61 solidarisée autour de l'écrou 60 et entraînée elle-même en rotation par une vis sans fin 70 dont le filet est de même inclinaison que le denture de la roue 61; l'axe de ladite roue 61 étant orthogonal à l'axe de la vis 70; cette dernière étant manoeuvrable manuellement ou automatiquement grâce à la présence d'une empreinte hexagonale 71, par l'intermédiaire d'un outil approprié tel un tournevis ou une clé.

25 Sur la figure 10, on peut remarquer que le dispositif de l'invention, une fois mis en place, ne présente aucune partie saillante ; la vis 120 est vissée dans la vertèbre 200, les seules parties proéminentes étant l'écrou 30 et le corps de l'implant 10.

Sur les figures 11 à 14a, les éléments d'ancrage sont des crochets 15 constitués d'une part du crochet proprement dit 151 et d'un corps 150 présentant une rainure 152 destinée à recevoir une tige, de la même manière que pour les implants vissés décrits précédemment.

La forme de la partie intérieure des crochets 151 dépend de leur emplacement sur les vertèbres ; leur partie extérieure présente un décrochement 153 prévu pour leur manipulation au moyen d'une pince représentée sur les figures 15 et 16.

Sur la figure 17 (a,b,c), on peut observer une agrafe destinée à faciliter la mise en place et le maintien des implants dans les vertèbres.

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Sur les figures 18 et 19, le dispositif de compression, de deux vertèbres, l'une par rapport à l'autre est constitué, dans une forme particulière de réalisation, d'une tige filetée 90 et de deux crochets 15, 16 conformes à ceux de l'invention et comportant en outre, chacun, un orifice cylindrique fileté de même pas que la tige filetée 90; les deux crochets 15, 16 étant de longueur différente, compte-tenu de la position inclinée des lames des vertèbres 200.

En position d'utilisation du dispositif, le corps 150 d'un des crochets 16 est fixé, de la manière sus-décrite, sur la tige d'étaiement 20, alors que le crochet est disposé sous la vertèbre inférieure et dirigé vers le haut; l'autre crochet 15 est placé sur la vertèbre supérieure dirigée 25 vers le bas, et peut coulisser le long de la tige 20 lorsqu'on visse la tige filetée 90 introdulte dans les orifices respectifs des crochets 15, 16 par l'intermédiaire d'un outil approprié ( non représenté), coopérant avec une empreinte 92 ménagée sur la tête de vis 91, afin de rapprocher les deux crochets 15, 16 l'un par rapport à l'autre; la fixation des crochets 15, 16 sur la tige 20 étant obtenue par l'intermédiaire d'un écrou 30, tel celui précédemment déconit

35 De tels implants peuvent être utilisés pour le montage de plaques à arthrodèse lambo-sacrée sous réserve que l'ex-

trémité supérieure de celles-ci comporte un tronçon de tiges de diamètre approprié permettant sa fixation aux implants fixés dans les vertèbres.

- 5 Sur la figure 20, le dispositif de raccordement longitudinal de tronçons de tiges 201 et 202, conforme à l'invention, est constitué d'une plaquette de raccordement 80 moletée sur ses deux faces, comportant deux orifices d'un diamètre correspondant à celui du corps 110 de la tête des implants 10 qui peuvent donc, sous réserve qu'elle soit séparée préalablement de sa vis 120, servir d'élément de raccordement des extrémités des tronçons de tiges 201 et 202, après que celles-ci aient été introduites dans la rainure de corps 110 constituant les éléments et que ceux-ci aient été introduits dans les orifices réalisés dans la plaquette. On comprend qu'il suffit ensuite de bloquer l'ensemble par l'intermédiaire des écrous 30 pour obtenir une solidarisation efficace des tiges 201 et 202.
- Sur les figures 21 et 22, on remarque que la liaison latérale des tiges 201 et 202 peut être aisément obtenue par l'intermédiaire d'une plaquette moletée spéciale 800 s'inspirant de celle 80 utilisée pour le raccordement longitudinal, représentée à la figure 20; elle en diffère par l'allongement de ladite plaquette et le remplacement de l'un des orifices de passage des corps 110 des têtes d'implant, par une rainure 801 de largeur correspondante permettant l'adaptation de la liaison à l'écartement des tiges imposé par la position des implants 10 dans le corps duquel, elles sont fixées.

Les implants et écrous sont en titane ou alliage de titane implantable ; ce qui élimine les problèmes d'allergie, de nécrose (l'os se désagrège autour de la vis et ne tient plus bien), que l'on connaît avec l'utilisation d'implants en acier inoxydable, tels ceux utilisés dans les dispositifs

connus.

Le dispositif est de mise en oeuvre aisée et rapide ; il est en effet passible de procéder au vissage des écrous autour 5 des corps des implants au moyen d'un outil approprié, de façon automatique.

La précision de la mise en place est accrue.

10 Bien entendu, l'invention n'est pas limitée au mode de réalisation qui vient d'être décrit et représenté. On pourra y apporter de nombreuses modifications de détail, sans sortir pour cela du cadre de l'invention.

#### Revendications

1. Dispositif de redressement et d'étaiement d'un rachis constitué d'implants vissés ou de crochets reliés par au 5 moins deux tiges solidarisées entre elles par l'intermédiaire d'éléments de raccordement et de liaison ; lesdites tiges étant introduites longitudinalement dans des rainures perpendiculaires à la vis, prévues à cet effet dans le corps des implants ou des crochets, puis bloquées dans 10 le fond des rainures, caractérisé en ce que la déformation par rapprochement des côtés (111,112) de la rainure, aménagée dans les corps (110,150) des implants (10) ou des crochets (15), afin d'obtenir le blocage de la tige (20 ou 21) dans le fond de la rainure, est obtenu par l'intermé-15 diaire d'un système à vis cylindrique (114) et à écrou à filetage conique (30), en ce que la solidarisation de la tige (20 ou 21) par rapport à la traverse filetée (40) est par l'intermédiaire de quatre (50,51,52,53) dont l'un (50) est fixé à l'une des extré-20 mités (41) de la traverse filetée (40), et dont la position des trois autres (51,52,53) sur la traverse est réglable par l'intermédiaire d'un écrou (60) maintenu dans une cage (531), dont la rotation s'obtient par l'intermédiaire d'un système roue (61) et vis sans fin (70), en ce que la fixation des vis (120) des implants (10) s'obtient 25 par l'intermédiaire d'un filet triangulaire (121) à 45°, dont l'un des côtés (122) situé en arrière par rapport à la pointe de la vis (120), forme un angle droit par rapport à la tige de ladite vis (120), en ce que les éléments de raccordement longitudinaux de tronçons (201,202) de tiges sont constitués d'une plaquette moletée (80) comportant deux orifices de passage du corps (110) de la tête d'implants (10) séparée ou non de sa vis (120), sur laquelle se monte un écrou (30) qui assure le blocage de l'ensemble, 35 en ce que les éléments de ligison latéraux des tiges (21,22) sont constitués d'une plaquette (800) comportant

un orifice de passage du corps (110) de la tête d'un implant (10), séparée ou non de sa tige, et une rainure de même largeur (801) permettant elle aussi, le passage du corps (110) de la tête d'un implant (10) et d'écrous (30) 5 assurant le blocage en position de l'ensemble et en ce que la tige filetée (90) de rappel de deux crochets (15,16), l'un vers l'autre, est montée dans des orifices filetées de même pas percés dans le corps (150) desdits crochets (15, 16).

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2. Dispositif selon la revendication 1, caractérisé en ce que le système à vis cylindrique (114) et à écrou conique (30) assurant le rapprochement des côtés du corps (110, 150) des implants (10) ou des crochets (15), est 15 constitué d'un filetage cylindrique mâle (114), réalisé autour du corps (110, 150) des implants (10) ou des crochets (15), à la profondeur de la rainure (113 ou 152), et d'un alésage conique fileté (310) de même pas, réalisé dans l'axe de l'écrou (30).

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3. Dispositif selon la revendication 2, caractérisé en ce que le diamètre de la base (311) de l'alésage conique fileté (318) de l'écrou (30) correspond au diamètre du filetage cylindrique mâle (114) réalisé autour du corps 25 (110,150) des implants (10) ou des crochets (15).

4. Bispositif selon les revendications 1 ou 2, caractérisé (113 30

nure.

- en ce que la hauteur de l'écrou (30) correspond approximativement à la distance séparant l'entrée de la rainure tige (20 ou 21), lors-152) de la que cette dernière est en place dans le fond de ladite rai-
- 5. Dispositif selon la revendication 1, caractérisé en ce que la tête (33) de l'écrou (30) est arrondie alors que sa base (32) comporte des dents (331) disposées oblique-

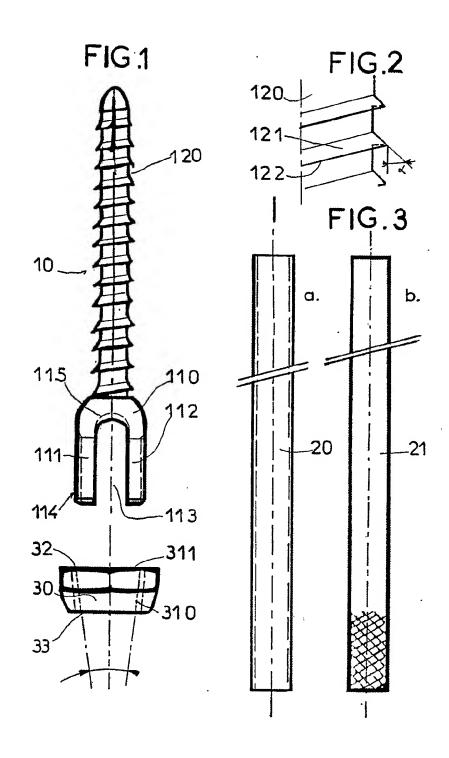
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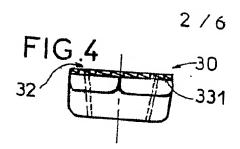
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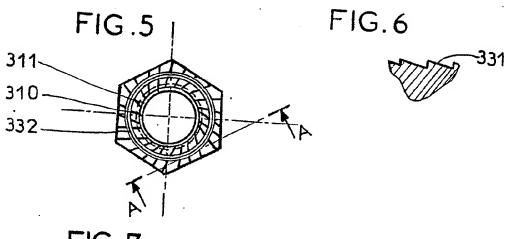
- 6. Bispositif selon la revendication 5, caractérisé en ce que la section des dents (331) de l'écrou (30) a la forme
  5 d'un triangle rectangle dont la base est confondue avec celle de l'écrou (30).
- 7. Dispositif selon la revendication 6, caractérisé en ce que l'hypoténuse du triangle rectangle est dirigée dans le 10 sens de rotation donné à l'écrou (30) pour obtenir le vissage et le serrage de celui-ci.
- 8. Dispositif selon la revendication 5, caractérisé en ce que les dents (331), disposées obliquement, sont striées
  15 selon des cercles (332) concentriques à l'axe de l'écrou (30).
- Dispositif selon la revendication 1, caractérisé en ce que la tige (20 ou 21) servant d'étais est filetée sur 20 toute sa longueur.
- 10. Dispositif selon les revendications 1 et 2 caractérisé, en ce que le fond de la rainure (113 ou 152) réalisée dans le corps (110) des implants (10) des 25 crochets (15), comporte une empreinte demi-cylindrique (115) dont le relief correspond à celui du filetage réalisé sur la tige étai (20).
- 11. Dispositif selon la revendication 1, caractérisé en ce30 que les implants (10) sont réalisés en titane pur Ti ou en alliage de titane implantable.
  - 12. Dispositif selon la revendication 11, caractérisé en ce que les implants sont réalisés en Ti A16 V4.
  - 13. Dispositif selon la revendication 1, caractérisé en ce

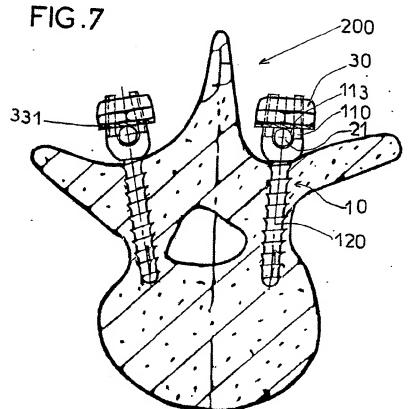
que la vis sans fin (70) d'entraînement de la roue (61) de manoeuvre de l'écrou (60), assurant le déplacement des mors mobiles (51,52,53) sur la traverse filetée (40), comporte un empreinte (71) permettant sa manoeuvre par l'intermédiaire d'un tournevis ou d'une clé.

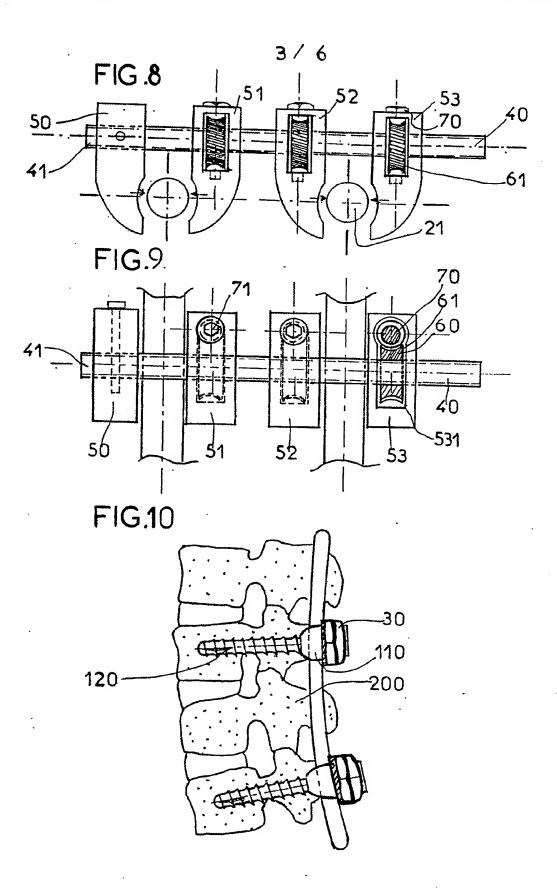
14. Dispositif selon la revendication 1, caractérisé en ce que le moyen de manoeuvre en rotation de la tige filetée de rappel (90) des crochets (15, 16), deux à deux, est constitué d'une empreinte (92) permettant sa manoeuvre par l'intermédiaire d'un tournevis ou d'une clé.

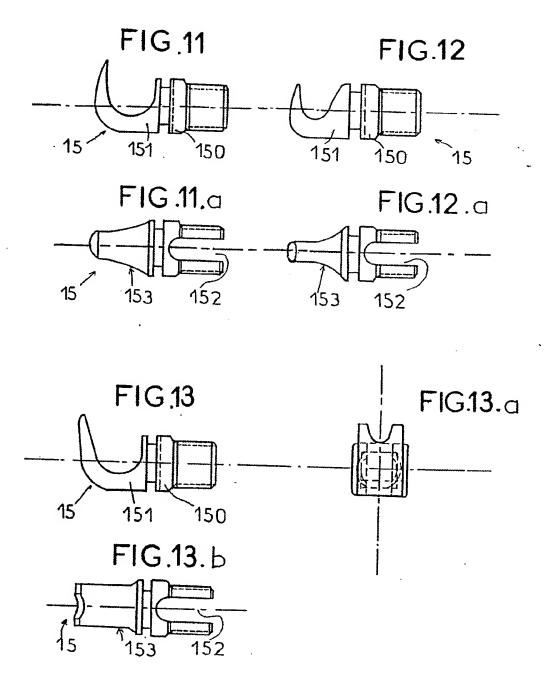




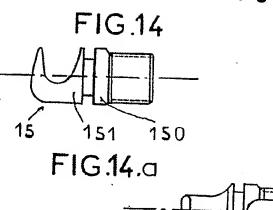








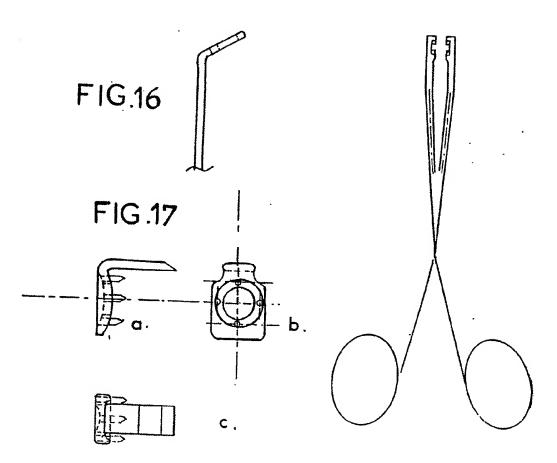




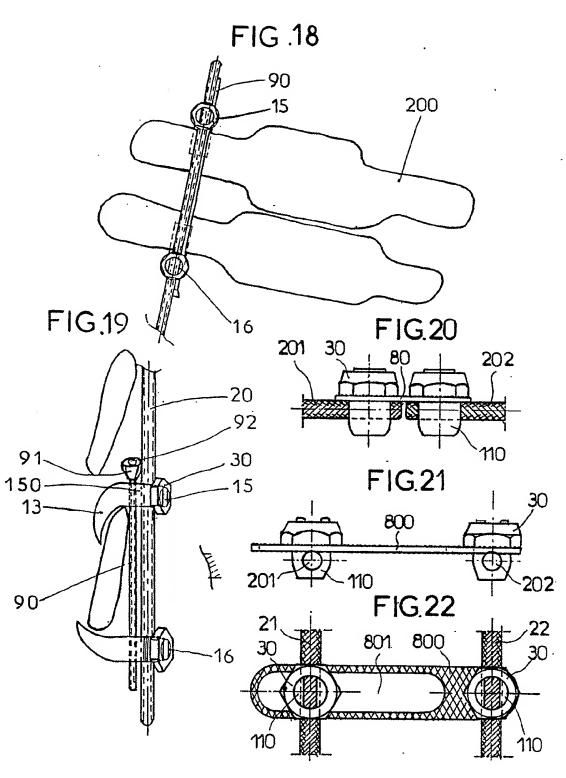
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	INTERNATIONAL S		/FR 90/00539
I. CLASSI	FICATION OF SUBJECT MATTER (if several classifi	cation symbols apply Indicate all)	
According to	to International Patent Classification (IPC) or to both Nation A61B 17/60, 17/18, F16B 35	nal Classification and IPC	37/00, 39/282
II. FIELDS	SEARCHED		
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Classification	n System (	lassification Symbols	
IPC <sup>5</sup>	A 61 B, F 16 B		
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	MENTS CONSIDERED TO BE RELEVANT		
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"A" docu cons: "E" earlie filing "L" docu which citati "O" docu other "P" docu	categories of cited documents: 10 ment defining the general state of the art which is not idered to be of particular relevance or document but published on or after the international date ment which may throw doubts on priority claim(s) or is cited to establish the publication date of another on or other special reason (as specified) ment referring to an oral disclosure, use, exhibition or means ment published prior to the international filing date but than the priority date claimed	"T" later document published after it or priority date and not in conflicted to understand the principle invention "X" document of particular relevant cannot be considered novel or involve an inventive step "Y" document of particular relevant cannot be considered to involve document is combined with one ments, such combination being of in the art. "A" document member of the same p	ct with the application but so theory underlying the as; the claimed invention cannot be considered to as; the claimed invention an inventive step when the or more other such docu- bylous to a person skilled
IV. CERTII			
	Actual Completion of the International Search	Date of Mailing of this International Se	arch Report
	tober 1990 (19.10.90)	12 November 1990 (	12.11.90)
Internationa	Searching Authority	Signature of Authorized Officer	
Europ	ean Patent Office		
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FR 9000539

SA 39013

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The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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Demande internationale N° PCT/FR 90/00539

I. CLASSEMENT DE L'INVENTION (si plusieurs symboles de classification sont applicables, les indiquer tous) 7					
Salon la classification internationale des brevats (CIB) ou à la fois selon la classification nationale et la CIB  S A 61 B 17/60, 17/18, F 16 B 35/06, 35/02, 2/06, 37/00, 39/282					
II. DOMA	NHES SUR LESQUELS LA RECHERCHE A PORTÉ	•			
	Documentation minimals cons	ultáa <sup>8</sup>			
Système	de classification Symboles	de classification			
CIB	CIB A 61 B, F 16 B				
	Documentation consultée autre que la documentation où de tels documents font partie des domaines sur le	in minimale dans la mesure squels la recherche à porté *			
// <b>DOO</b>					
	MENTS CONSIDÉRÉS COMME PERTINENTS 19				
Catégorie *	identification des documents cités, 11 avec indication, des passages pertinents 12	si.nécessaire, N° des revendications visées 19			
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considéré comme particulièrement partinent de la technique pertinent, mais cité pour comprendre le principe ou la théorie constituant la base de l'invention					
tionsi ou après cette date  «X» document particulièrement pertinent: l'invention revendi- quée ne peut être considérée comme nouvelle ou comme impliquant une activité inventive					
autre citation ou pour une raison spéciale (taile qu'indiquée)					
<ul> <li>« O » document se référant à une divulgation orale, à un usage, à une exposition ou tous autres moyens</li> <li>« P » document publié ayant la date de dépôt international, mais</li> <li>odque ne peut etre considère comme impliquant une activité inventive lorsque le document est associé à un ou plusieurs autres documents de même nature, cette combinaison étant évidente pour une personne du mêtier.</li> </ul>					
posterieurement à le date de priorité revendiquée « de document qui fait partie de la même famille de bravets					
IV. CERTIFICATION  Date à laquelle la recherche internationale a été effectivement achevée  Date d'expédition du présent rapport de racherche internationale					
19 octobre 1990 4 2 NAV 1990'					
Administration chargée de la recherche internationale OFFICE EUROPEEN DES BREVETS Signature du fonctionneite ruforiale					

# ANNEXE AU RAPPORT DE RECHERCHE INTERNATIONALE RELATIF A LA DEMANDE INTERNATIONALE NO.

FR 9000539 SA 39013

La présente annexe indique les membres de la famille de brevets relatifs aux documents brevets cités dans le rapport de recherche internationale visé ci-dessus.

Lesdits membres sont contenus au fichier informatique de l'Office européen des brevets à la date du 05/11/90

Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsabilité de l'Office européen des brevets.

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(71) Applicant (for all designated States except US): DANNING-ER MEDICAL TECHNOLOGY, INC. [US/US]; 1145 Chesapeake Road, Columbus, OH 43212 (US).

(72) Inventors; and

(75) Inventors, and (75) Inventors/Applicants (for US only): PUNO, Rolando, M. [US/US]; 8204 Pipilo Place, Louisville, KY 40242 (US). MELLINGER, Phillip, A. [US/US]; 1094 Kirk Avenue, Worthington, OH 43085 (US).

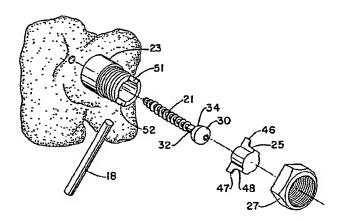
(74) Agents: GALLOWAY, Peter, D. et al.; Ladas & Parry, 26 West 61 Street, New York, NY 10023 (US).

(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE\*, DE (European patent)\*, DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.

**Published** 

With international search report.

(54) Title: TRANSPEDICULAR SCREW SYSTEM AND METHOD OF USE



#### (57) Abstract

An apparatus is provided for the internal fixation of the spine. The apparatus comprises two sets of implants (8) each consisting of a rod (18) and a plurality of vertebral anchors (16). The rod (18) is secured to the vertebral elements by the vertebral anchors (16). The anchor (16) includes a transpedicular screw (21) which is secured to a vertebrae. The anchor (16) further includes an anchor seat (23) which captures the screw (21) and permits micromotion between the anchor seat (23) and screw (21). This seat (23) has a rod-receiving channel (51, 52) which captures the rod (18). A cap (25) cooperates with the seat (23) to secure the rod (18) in the anchor (16). A nut (27) screws down from the top of the assembly onto the seat (23) to cause rod (18) receiving flanges (46, 47) in the cap (23) to apply a compressive force to the rod (18). A method of therapy is presented in which the present implants (8) are inserted surgically into a patient.

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WO 91/16020

Transpedicular screw system and method of use

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This invention relates generally to an apparatus for immobilization of the spine, and more particularly, to an apparatus for posterior internal fixation of the spine as well as to a method of therapy which utilizes the device.

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Various methods of spinal immobilization have been known and used during this century in the treatment of spinal instability and displacement. The preferred treatment for spinal stabilization is immobilization of the joint by surgical fusion, or arthrodesis. method has been known since its development in 1911 by Hibbs and Albee. However, in many cases, and in particular, in cases involving fusion across the lumbosacral articulation and when there are many levels involved, pseudoarthrosis is a problem. It was discovered that immediate immobilization was necessary in order to allow a bony union to form. Early in the century, post operative external immobilization such as the use of splints and casts was the favored method of treatment, however, as surgical techniques have become more sophisticated, various methods of internal and external fixation have been developed.

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Internal fixation refers to therapeutic methods of stabilization which are wholly internal to the patient and include commonly known devices such as bone plates and pins. External fixation in contrast involves at least some portion of the stabilization device which is external to the patient's body. Internal fixation is now the favored method of immobilization since the patient is allowed greater freedom with the

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elimination of the external portion of the device and the possibility of infections, such as pin tract infection, is reduced.

Some of the indications treated by internal fixation of the spine include vertebral displacement and management such as kyphosis, spondylolisthesis and rotation; segmental instability, such as disc degeneration and fracture caused by disease and trauma and congenital defects; and tumor diseases.

A common problem with spinal fixation is the question of how to secure the fixation device to the spine without damaging the spinal cord. The pedicles are a favored area of attachment since they offer an area that is strong enough to hold the fixation device even when the patient suffers from osteoporosis. Since the middle 1950's, methods of fixation have utilized the pedicles. In early methods, screws extended through the facets into the pedicles. More recently, posterior methods of fixation have been developed which utilize wires that extend through the spinal canal and hold a rod against the lamina (such as the Luque system) or that utilize pedicular screws which extend into the pedicle and secure a plate which extends across several vertebral segments (such as the Steffee plate).

U.S. Patent No. 4,805,602 to Puno, et al presents a system sharing advantage of both the wired implants and the plate. Specifically, that screw and rod system provides a rigidity which is intermediate between the wired implant and the plate systems and may be contoured to any plane.

The present invention represents an improvement in the technology and in the therapy advanced in `U.S. Patent No. 4,805,602. In particular, this invention greatly reduces the time required to perform the 'spinal operation as compared to the prior invention. As an example of such a reduction, the time for inserting the anchors may be cut from hours to around an hour.

WO 91/16020 PCT/US90/02286

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Such a time saving represents a significant reduction in the risk associated with a surgical procedure. Further, the new design may be easier to use as the chances of cross-threading the nut unto the anchor are reduced and the nut is more accessible for tightening. This is of particular significance in the bloody environment which obscures the spinal surgeon's access to the fixation device. The present device achieves this accessibility and attendant time savings without sacrificing the mechanical benefits of the earlier design. In particular, the anchor is designed so that it is not overly More specifically, the nut is thin and obtrusive. further is chamfered to reduce bulk and yet includes a thread design to achieve sufficient compression on the The anchor system presents a flush upper surface and the total system is elegant and effective. anchor seat is secured by a cancellous screw which cooperates through a sloped bore in the anchor seat so as to provide a limited ball and socket motion. design of the present invention incorporates a method of therapy for treating a spinal indication utilizing this internal fixator.

In particular, the present invention is viewed as having an application in the stabilization of the thoracolumbar, lumbar, and sacral spine. There are problems of fixation unique to this area of the spine such as the fact that the lumbar spine is normally lordotic and this lordosis must be preserved. In addition, indicated spinal decompression often requires a destabilization of the spine posteriorly. This may result in instability unless fusion is done, and fusion will often fail to become solid unless effective internal fixation is used. Finally, the points of sacral fixation are the weakest point of fixation. These problems are addressed by the present invention.

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Prior art devices for posterior spinal fixation are discussed above as including the Steffee plate and the Luque System. A complete discussion of various internal devices are included in L. Wiltse, "Internal Fixation of the Lumbar Spine," Clinical Orthopaedics and Related Research, February 1986, No. 203, pp. 2-219. Known implant configurations include facet screws, double distraction systems, compression distraction systems, springs, spinous process plates, wired implants and transpedicular screw and plate systems.

Common distraction and compression systems utilize a threaded rod and hooks which engage selected transverse lamina of the vertebrae. Examples of such systems include the Harrington distraction system sold by Zimmer USA, Inc., the Keene system shown in U.S. Patent No. 4,269,178 and the Lewis-Greenlaw System illustrated in U.S. Patent No. 4,085,744. U.S. Patent No. 3,648,691 to Lumb, et al shows the use of spinous process plates.

Wired implants are favored by some orthopedic surgeons because of the flexibility of the system. Dr. Eduardo Luque has developed a wired implant system where two L-shaped rods are secured along their long sides to the vertebral laminae by means of wires which pass through the vertebral foramina. The short legs of the rods extend across the vertebrae between the spinous process. A similar wired implant is shown in U.S. Patent No. 4,604,995 to Stephens, et al.

Transpedicular screw and plate systems rely on a screw threaded into a reamed canal generally positioned perpendicular to the longitudinal axis of the spine and horizontal or parallel to the transverse plane of the vertebral body. The screws engage a plate which has been bent to conform to the normal curvature of the spine or to the points of desired reduction. One screw

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and plate system which has been used with significant success is the Steffee system. In this system, the screws are inserted first, the spine plates are then inserted over the pedicle screws and then posterior tapered nuts are screwed on. The screws are tightened bilaterally until the plate is locked between two nuts.

While the wired implants have the advantages of facilitating vertebral alignment, permitting variation of the device to allow for variations in individual spines, this method of fixation includes the increased risk of damage to the neural structures. This risk can be countered by the use of transpedicular screws and The pedicle presents an area for fixation of plates. sufficient size and depth, that under careful conditions, the risk of damage to the neural elements (i.e., spinal cord and or nerve roots) is reduced. other hand, the use of plates with the screws rigidly linked results in the direct transfer of loads at the bone-screw interface which is the weakest link in the fixation spine construction. This can result in breakage of the screw or failure of the bone-screw interface prior to achieving fusion. In addition, the current plate designs are bulky and leave little surface for bone grafting and they cannot be contoured to account for lateral curvature of the spine (i.e., scoliosis).

The present invention utilizes a rod and vertebral anchors which holds the rod in position. Each anchor is secured to the vertebrae by a transpedicular screw member.

The screw and rod system of the present. invention combines favorable attributes discussed above of wire implants and of screw plate systems. In particular, the present invention has an object of providing a fixation system which adequately immobilizes

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the lumbosacral area, allows relatively simple and riskfree insertion and provides adequate area for bone grafting.

Thus, the present invention combines advantages of the known devices as it provides suitable immobilization, in particular of the lumbosacral region, it allows for adaptation to individual patient characteristics such as degree of sagittal and/or coronal plane curvature; it allows for safe and relatively risk-free insertion; and it permits sufficient area for bone grafting.

Further, the present invention presents an improvement over the previous rod and anchor system as it streamlines the surgical procedure and increases the ease of insertion while maintaining the favorable attributes of the other system. Specifically, one less part is required and less time is required in preparation of the bony surface to receive the implant.

In order to achieve these advantages, the present design utilizes two implant sets on either side of the spinous processes. Each implant set includes a 0.25 inch diameter stainless steel (316L) rod which spans the vertebrae to be immobilized. Generally, an implant set is used on each side of the spinous process on the posterior side of the lamina and the transverse The rod is held in position by a stainless process. steel vertebral anchor which captures the rods. anchor has a seat member which is secured to the vertebrae by a stainless steel transpedicular screw. screw is separate from the anchor seat and thus provides for limited motion between the anchor seat and the vertebrae. In addition, this aspect of the design acts as a "shock-absorber" to prevent direct transfer of load from the rod to the bone-screw interface prior to achieving bony fusion, thereby decreasing the chance of failure of the screw or the bone-screw interface prior to achieving bony fusion. This greatly facilitates the

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surgical procedure and therapy incorporating this device.

In the preferred embodiment, the anchor comprises three members; an anchor seat having a bore which receives the screw and a rod-receiving channel transverse to the screw; a cap which mates with the anchor seat to capture the rod between the rod receiving channel and the cap; and an internally threaded collar or nut which engages external threads on the anchor seat to tighten the cap into position on the rod support as it is screwed downward into position on the anchor seat.

FIG. 1 is a side view of a spine with the invention in place;

FIG. 2 is a side plan view of the vertebral anchor and rod of the present invention;

FIG. 3 is a posterior view of a vertebral body with an exploded view of the fixation device of the invention;

FIG. 4 is a cross-sectional of the anchor seat along line 4-4 with the rod shown in phantom;

FIG. 5 is a top plan view of the assembly;

FIG. 6 is a cross-section of the assembly shown in FIG. 4 taken along line 6-6;

FIG. 7 is a cross-section of the anchor seat and nut with the cap and screw and the rod shown in phantom;

FIG. 8 is a top view of the crosslink of the present invention;

FIG. 9 is a cross-section taken along line 9-9 of FIG. 3;

FIG. 10 is a cross-section taken along line 10-10 of FIG. 8;

FIG. 11 is a cross-section of the set screw;

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FIG. 12 is a posterior view of the placement of the awl;

FIG. 13 is a cross-section of a vertebrae showing placement of the pedicle probe;

FIG. 14 is a side view showing the placement of the trial seats;

FIG. 15 is a cross-section of a vertebrae showing implantation of the anchor seat and transpedicular screw using a seat holder and hexagonal screw driver;

FIG. 16 is a cross-section of a vertebrae showing the transpedicular screw and the seat in position;

FIG. 17 is a posterior view showing installation of the rod and cap using the rod holder and cap holder;

FIG. 18 is a posterior view showing tightening of the nuts on the anchor seats;

FIG. 19 is a posterior view showing installation of the crosslinks; and

FIG. 20 is a posterior view showing positioning of the joining link between the crosslink and tightening of the set screw in the crosslink.

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The anchor screw and rod system 10 of the present invention includes two implant sets 8 on either side of the spinous processes. Each set is comprised of a plurality of vertebral anchors 16 and a rod 18 which is of sufficient length to span the length of spine to be immobilized.

Each anchor 16 is positioned on the dorsal side of the vertebra and in general, a separate anchor 16 is used for each vertebrae comprising the length of spine to be stabilized. The rod 18 is held by the anchors 16 posterior to the vertebra.

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The rod 18 is generally made of quarter inch stainless-steel rod (316L), but could be made of any material which has suitable biocompatibility and material strength characteristics. The rod should be able to withstand lateral bending forces and torsion since the system may be used to correct spinal displacement and curvature. On the other hand, it is important that the rod 18 can be bent to a certain extent so that the rod can be bent to the proper curvature for the individual application.

The vertebral anchor 16 comprises a transpedicular screw 21, an anchor seat 23, a cap 25, and a nut 27. The various anchor parts 16 can be made of any suitably strong biocompatible material such as stainless steel. The screw 21 which is shown is a standard stainless steel cancellous screw with 6.5 mm thread diameter. It is available in various lengths. The anchor 16 was designed for use with this screw since the screw is readily available, and it has a proven record in fracture fixation; and the size can be accommodated by the average adult pedicles of the lower thoracic, lumbar and the upper two sacral segments vertebrae.

The screw 21 includes a head 30 which accommodates a hex driver. The screw 21 includes a smooth shank 32 of 2-4 millimeters length which joins the rounded rear shoulder 34 of the head 30. After insertion, the screw 21 extends from the curve formed on the dorsal side of the posterior neural arch.

The anchor seat 23 is comprised of a hollow cup portion 49 which receives the screw and which includes opposing channels 51,52 to receive the rod 18. The cup 49 has a stepped central longitudinal opening 40 having an upper inner diameter section of about 0.358 and a smaller lower diameter section which slightly exceeds the diameter of the head 30 of the screw 21. This step eliminates unwanted motion between the screw 21 and the anchor 23. This lower diameter section is

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about 0.323 of an inch. The screw 21 passes through the two sections of the opening 40 within the rod support 23 until the rear shoulder 34 of the screw 21 encounters a detaining flange 42 within the central opening 40 of the rod support 23. The flange 42 has an internal surface at an angle of about 120 degrees and defines an opening 43 which has a diameter that exceeds the diameter of the shank 32 but which is smaller than that of the head 30 of the screw 31. The diameter of the opening at the flange is about 0.27 of an inch. The internal surface of the detaining flange 42 represents a sloped shoulder 44 which forms a socket for the rear shoulder 34 of the Thus, when the screw 21 engages the screw head 30. anchor seat 23, a limited ball-and-socket joint is formed which permits freedom of movement between the rod support 23 and the screw 21.

The anchor seat 23 has two opposing channels 51,52 of the proper diameter to cradle the rod 18. The channels 51,52 form a rod-receiving cradle which is about 0.37 of an inch long.

The height of the anchor seat 23 generally determines the amount that the anchor 26 projects posterior of the vertebrae. This height ranges from 0.66 to 0.84 inches. However, if necessary, one or two washers may be added. These washers are smooth round washers having an outer diameter which corresponds to the diameter of the anchor seat, i.e., 0.5 inch, and a height of 0.063 inch. The washer fits around the screw 21 and is positioned under the seat between the bone and the seat 23. The washers are useful in indications where the patient is heavy or severely deformed.

On its external surface, the anchor seat 23 includes a threaded area 76. This area is 0.27 inch deep to the thread runout. A 45 degree chamfer is included at the top to facilitate threading the nut on the seat 23. The threads are at a count of 20 threads per inch. The nut 25 has a height of 0.19 inch and

WO 91/16020 PCT/US90/02286

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includes a chamfered area 81 on its top surface. This chamfered area 81 blunts the edges of the nut and eliminates sharp edges which could otherwise irritate the soft tissues post-operatively, two opposing clamping flanges 46,47 which each extend about 0.13 inch beyond a larger diameter area 46 of the cap 25. Two such larger diameter areas 48 exist and form opposing buttressing curves where the flanges 46,47 flow into the cup portion 59 of the cap 25. These two areas 48 mate with the channels 51,52 so that the seat 23 and the cap 25 complement each other to form a cylindrical unit into which the nut 27 is threaded. On its bottom, the cap 25 includes an arch 72 transverse to the longitudinal axis of the cap 25.

The nut 27 includes internal threads 83 which engage the external threaded area 76 on the anchor seat. The nut 27 is a hex nut which can be tightened relative to the seat 25.

As the nut 27 is rotated about the anchor seat 25, it cooperates with the top side of the flange 46,47 to tighten the clamp 25 in relation to the rod support 23. The rod 18 is grasped in the tunnel 84 formed between the rod-receiving channel 54 of the anchor seat 23 and the arch 72 of the cap 25.

As a further part of this invention, a crosslink 110 may be used to stabilize the rod members 18 against torsional rotation. The crosslink 110 may be used with this implant device or with any spinal implant which utilizes rods for longitudinal stability such as the Harrington rod system. It is preferable that two crosslinks are used to form a rectangular construct. Each crosslink 110 comprises two clamps 112, each secured to the main rods 18. Specifically, each clamp . 112 includes a rod receiving channel 113 which accommodates the rod 18 and is locked into position relative thereto by a first set screw received in bore 114. The clamp further includes a link opening 118 which has a

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well 119 to accommodate a link 117 axially transverse to the main rod 18. This link 117 may be, for example, a 4 mm Steinmann pin. The link 117 is locked into position by a second set screw which biases the link 117 into the well 119. The set screws 115 include a hexagonal opening 120 to receive a corresponding screw-driver. The screws 115 further include a terminal bevel at a 45 degree angle to facilitate locking the rod and link, respectively.

A method of therapy for use of the present device is described as follows:

Initially, the area of implantation is surgically approached. A longitudinal posterior midline incision is made over the spine. The incision is carried through the subcutaneous tissue and the fascia to the tips of the spinous processes. Subperiosteal dissection is performed over the laminae and transverse processes. The facet capsule and articular cartilage are removed in preparation for fusion.

The pedicle is located using an awl 80. The awl 80 is used to make a hole 4 mm deep at the intersection of a line drawn transversely through the midportion of the transverse process and a line drawn longitudinally through the lateral margin of superior articular facet.

A pedicle hole is made using a pedicle probe 85. The pedicle probe is inserted into the hole initially created by the awl 80 and rotated back and forth in a 90 degree arc of motion with a very gentle downward pressure. The surgeon feels a relatively soft gritty sensation of the cancellous bone within the pedicle and vertebral body during this procedure. The shaft of the probe 85 should end up at an angle of 10 to 15 degrees from the midline of the spine when used in the lumbar region. Great care should be taken not to penetrate the anterior cortex of the vertebral body with the probe 85.

WO 91/16020 PCT/US90/02286

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The depth of the hole is determined by using the graduated markings on the pedicle probe 85. The appropriate size screw is then chosen for that particular pedicle. The same technique is repeated for the remaining pedicles that need to be instrumented. Roentgenographic assistance using plain radiographs or fluoroscopy may be recommended for proper insertion of the pedicle probe 85 and screw into the pedicle. Both anterior-posterior and lateral views are taken with metal markers in the holes of the pedicles to assure proper hole direction prior to insertion of the screws.

After the hole has been created, one of four sizes of anchor seats is then selected depending on the height needed for the rod to rest above the fusion bed. Trial anchors 91 may be inserted on rods 92. Washers are provided if additional height is needed.

The surgeon sequentially inserts an appropriate transpedicular screw 21 and anchor 23 seat assembly into each pedicle being instrumented. This is accomplished by using a hexagonal screwdriver 97. At the same time, the seat holder 98 grips the seat, thereby preventing rotation when the screw 21 is finally tightened.

After all the screws and anchor seats are in place, an appropriate length of 6.35 mm rod is chosen and contoured with a French bender to fit the seats. The rod 18 is placed using a rod holder 100 and secured on the seats with caps which are placed over the rod using a rod holder 101 and nuts which are tightened down over the cap with the use of a T-wrench 105.

The procedure is repeated on the other side of the spine over the same number of vertebral levels.

Finally, the crosslinks 110 may be applied for added torsional stability. The crosslink is composed of two clamps 112, each of which is secured to one of the two main rods with set screws 115. The clamps are then bridged together by a 4 mm Steinmann pin which acts as

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a crosslink 117 which is cut to the length equivalent to the distance between the clamps. The Steinmann pin is secured to the clamp 117 with a second set screw. It is recommended that at least two sets of crosslinks are used to provide a more stable construct.

In the case of arthrodesis, the fusion portion of the procedure is carried out in standard fashion. However, it is recommended to place some of the bone grafts in the lateral gutter after making the pedicle hole prior to screw insertion. The presence of the instrumentation can block the visualization of the fusion bed necessary for the proper placement of the graft. The remainder of the bone grafts are placed on the fusion bed after the instrumentation is completed.

While in accordance with the Patent Statutes, the best mode and preferred embodiment has been set forth, the scope of the invention is not limited thereto, but rather by the scope of the attached claims.

WO 91/16020 PCT/US90/02286

#### - 15 -

#### CLAIMS

- A fixation device for the stabilization of one or 1. more bone segments, comprising at least two anchors and an elongated stabilizer, said anchors each comprising screw means which secures said anchor to said bone segment, anchor seat means which has a lower bone interface which is operatively joined to said bone segment by said screw means and has a portion spaced apart from said bone interface surface and said anchor seat means cooperating with said screw means so as to permit limited motion between said screw means and said anchor seat means, said anchor seat means further having means to receive said stabilizer, cap means which cooperate with said anchor seat means to capture said stabilizer, and securing means which cooperates with said anchor seat portion which is spaced apart from said bone interface surface and which is posterior to said rod and said seat and said screw means cooperating to allow relative limited motion whereby alignment of the rod-receiving channels is facilitated and transfer of load from the rod to the interface of the spine and the screw is inhibited.
- 2. A fixation device according to claim 1, wherein said anchor seat means includes an internal bore through which said screw means projects, and wherein said screw means comprises a screw having a rounded head and said internal bore terminates in an annular flange which cooperates with said rounded head.
- 3. A fixation device according to claim 2, wherein said anchor seat means includes external threads and said securing means comprises a nut having internal threads and said internal threads cooperate with said external threads to secure said nut to said anchor seat means, and wherein the anchor seat means has a channel to receive said rod and said cap means has an opposing larger diameter portion which complements said channel and said larger diameter portion terminates in rod receiving flanges and said nut cooperates with said rod receiving flanges to apply said

compression force to said rod.

- 4. A fixation device according to claim 3, wherein said lower bone interface surface of said anchor seat means has a diameter of less than about 0.6 inch and said anchor projects less than 0.95 inch from said bone surface.
- A device for the stabilization of one or more 5. bone segments, comprising at least two anchors and a rod, said anchors each comprising a screw, an anchor seat, a cap, and a nut, said screw having a shank joined to a head, said head having a rounded profile where it joins said shank; said anchor seat having an internal bore, said screw projecting through said bore to be received by said bone segment and said bore including a shoulder which cooperates with the rounded profile of the screw head and said anchor seat further including external threads and a channel to receive said rod; said cap having a smaller outer diameter portion which is received within said anchor seat bore and a large outer diameter portion forming at one end an arch including opposing rod holding flanges; said larger outer diameter portion mating with said rod receiving channel whereby said rod is captured between said arch and said channel; and a nut including top and bottom surfaces and having internal threads which mate with the external threads of the anchor seat and said nut being posterior to said rod and tightening down toward rod whereby said bottom surface engages said opposing rod holding flanges and causes said cap to apply a compressive force to said rod.
- 6. A device according to claim 5, wherein said device comprises two sets of implants, each of said implant sets comprising a rod and at least two of said anchors.
- 7. A device according to claim 6, wherein said device further comprises two crosslinks, each of which links the rod of one implant set to the rod of the other implant set.
- 8. A method of therapy comprising the surgical implantation of a fixation device in a spine, said fixation device comprising a rod and at least two anchors, each of

WO 91/16020 PCT/US90/02286

- 17 -

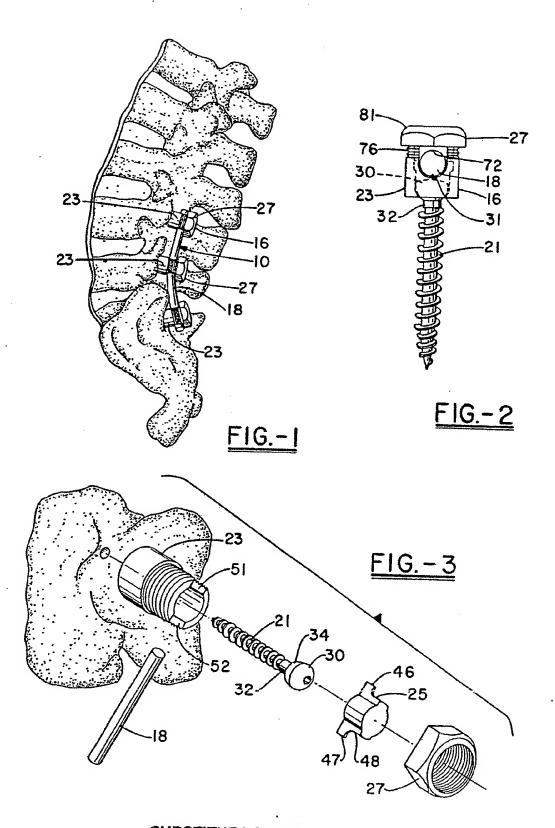
said anchors having screw means, seat means forming a rod receiving channel, cap means including a rod-holding arch and securing means, said method comprising the steps of exposing the area including at least two vertebrae of spine to be implanted, preparing the bone of said area by < flattening a surface to receive each of said seat means and by forming a hole in the pedicle of each vertebrae to receive each of said screw means, joining each of said seat means to each of said pedicles by screwing each said screw means in each of said holes, aligning the rod receiving channels of each of said seat means and inserting said rod within said channel, placing a cap over the rod for each anchor so that the rod holding arch of each cap cooperates with the rod receiving channel of each seat means and to encircle said rod so that the cap mates with the seat, tightening a securing means for each of said anchors so that the anchor applies a compressive force on said rod and said seat and said screw means cooperating to allow relative limited motion whereby alignment of the rodreceiving channels is facilitated and transfer of load from the rod to the interface of the spine and the screw is inhibited.

9. The use of a device for the stabilization of one or more bone segments, said device comprising at least two anchors and an elongated stabilizer, said anchors each comprising screw means which secures said anchor to said bone segment, anchor seat means which has a lower bone interface which is operatively joined to said bone segment by said screw means and has a portion spaced apart from said bone interface surface and said anchor seat means cooperating with said screw means so as to permit limited motion between said screw means and said anchor seat means, said anchor seat means further having means to receive said stabilizer, cap means which cooperate with said anchor seat means to capture said stabilizer, and securing means which cooperates with said anchor seat portion which is spaced apart from said bone interface surface and which is

posterior to said rod and said seat and said screw means cooperating to allow relative limited motion whereby alignment of the rod-receiving channels is facilitated and transfer of load from the rod to the interface of the spine and the screw is inhibited.

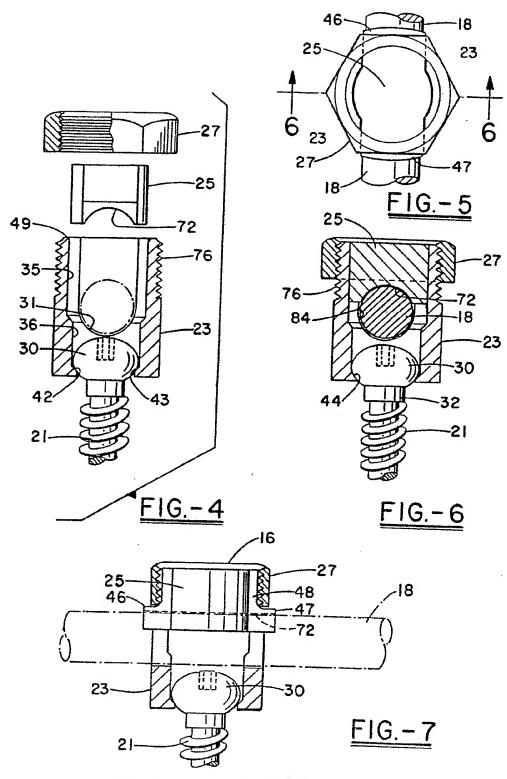
The use of the following components to create a 10. device for the stabilization of one or more bore segments, said components including at least two anchors and an elongated stabilizer, said anchors each comprising screw means which secures said anchor to said bone segment, anchor seat means which has a lower bone interface which is operatively joined to said bone segment by said screw means and has a portion spaced apart from said bone interface surface and said anchor seat means cooperating with said screw means so as to permit limited motion between said screw means and said anchor seat means, said anchor seat means further having means to receive said stabilizer, cap means which cooperate with said anchor seat means to capture said stabilizer, and securing means which cooperates with said anchor seat portion which is spaced apart from said bone interface surface and which is posterior to said rod and said seat and said screw means cooperating to allow relative limited motion whereby alignment of the rod-receiving channels is facilitated and transfer of load from the rod to the interface of the spine and the screw is inhibited.

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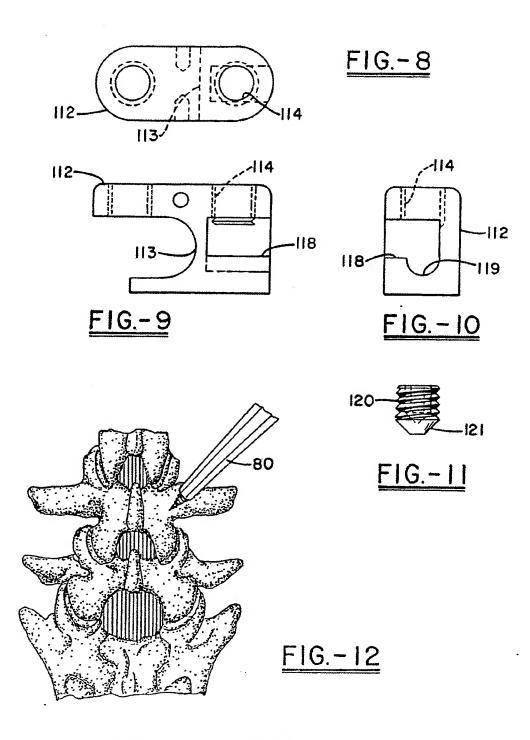


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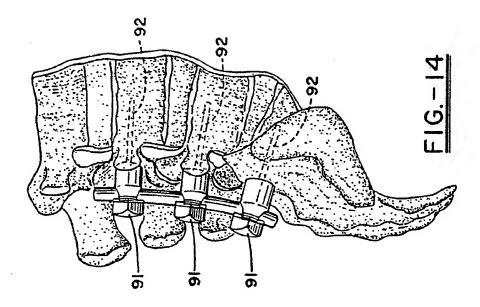


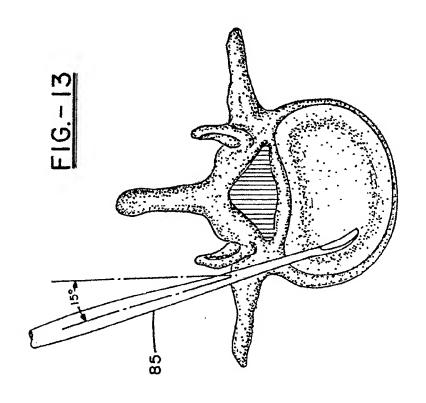
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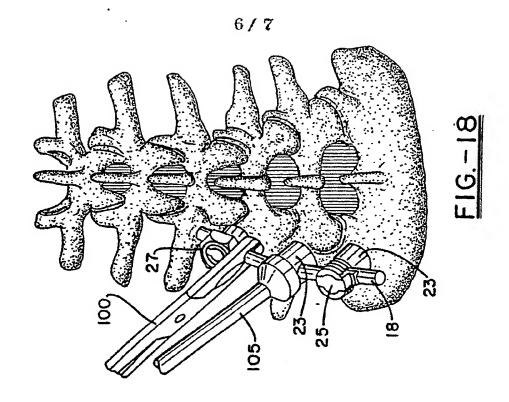
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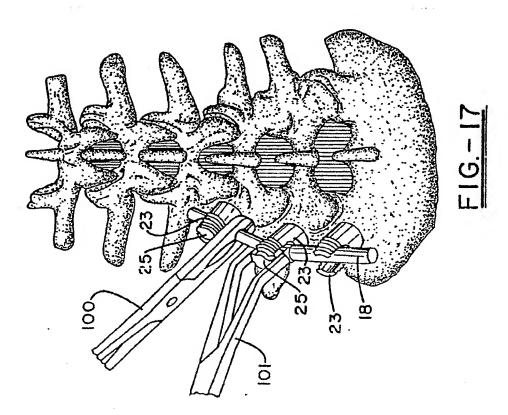
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## INTERNATIONAL SEARCH REPORT

International Application No PCT/US90/02286 I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 1 According to International Patent Classification (IPC) or to both National Classification and IPC IPC (5): [A61F/500] A61F 5/00 U.S. CL: 128/69, 606/61 II. FIELDS SEARCHED Minimum Documentation Searched 4 Classification System j Classification Symbols U.S. 403/342,399; 411/400,401 606/60,61,72,73; 623/16,17; 128/69 Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched # IIL DOCUMENTS CONSIDERED TO BE RELEVANT 14 Category • Citation of Document, to with indication, where appropriate, of the relevant passages 17 Relevant to Claim No. 19  $\frac{X}{Y}$ 4,805,602 (PUNO ET AL.) 21 February 1989 1-2 See the entire document. 3-10 Α 4,653,481 (HOWLAND ET AL.) 31 March 1987 US, A. 1-10 See the entire document. A US, A, 4,719,905 (STEFFEE) 19 January 1988 1-10 See the entire document. A US, A, 4,658,809 (ULRICH ET AL.) 21 April 1987 1-10 See the entire document. Α US, A. 4,611,580 (WU) 16 September 1986 1-10 See the entire document. A US, A, 4,913,134 (LUQUE) 03 April 1990 1-10 See the entire document. A US, A, 4,763,644 (WEBB) 16 August 1988 See the entire document. \* Special categories of cited documents; 13 later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filling data "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person shilled in the art. document referring to an oral disclosure, use, exhibition or document published prior to the international filing date but later than the priority date claimed "4" document member of the same patent family IV. CERTIFICATION Date of the Actual Completion of the International Search Date of Mailing of this International Search Report 5 08 AUGUST 1990 International Searching Authority I Signature of Authorized Officer 20 MICHAEL A. BROWN

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Mit internationalem Recherchenbericht.

(54) Title: IMPLANT FOR OSTEOSYNTHESIS DEVICE, IN PARTICULAR FOR CORRECTING THE VERTEBRAL COLUMN

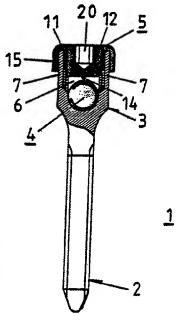
(54) Bezeichnung: IMPLANTAT FÜR EINE OSTEOSYNTHESEVORRICHTUNG, INSBESONDERE ZUR WIRBELSÄU-LENKORREKTUR

#### (57) Abstract

An implant for an osteosynthesis device, in particular for correcting the vertebral column, has a lower bone anchoring part (2) and an upper part (3) that can be detachably fastened to a longitudinal support (4). The upper part (3) has an upward open channel (6) that extends backwards and defines two lateral branches (7) provided with an inner thread (10) for receiving the longitudinal support (4). In addition, a clamping part (5) for the longitudinal support (4) has a cover (11) with coaxial, outer rims (15) for enclosing the branches (7) and a coaxial inner cylinder (12) to be introduced between the branches (7). The outer surface of the envelope of the inner cylinder (12) has an outer thread (13) that corresponds to the inner thr. id (10) of the upper part (3).

## (57) Zusammenfassung

Dieses Implantat für eine Osteosynthesevorrichtung, insbesondere zur Wirbelsäulenkorrektur weist einen unteren Teil (2) zur Knochenverankerung und einen oberen Teil (3) zur lösbaren Fixierung mit einem Längsträger (4) auf. Der obere Teil (3) besitzt einen von vorn nach hinten verlaufenden, nach oben offenen Kanal (6), der zwei seitliche Schenkel (7) zur Aufnahme des Längsträgers (4) bestimmt, welche mit einem Innengewinde (10) versehen sind. Zusätzlich ist ein Klemmteil (5) für den Längsträger (4) vorgesehen, der einen Kappenteil (11) mit koaxialer, äusserer Krempe (15) zur Umschliessung der Schenkel (7) sowie einen koaxialen Innenzylinder (12) zur Einführung zwischen die Schenkel (7) umfasst, wobei die äussere Mantelfläche des Innenzylinders (12) ein mit dem Innengewinde (10) des oberen Teils (3) korrespondierendes Aussengewinde (13) aufweist.



## LEDIGLICH ZUR INFORMATION

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# Implantat für eine Osteosynthesevorrichtung, insbesondere zur Wirbelsäulenkorrektur.

Die Erfindung bezieht sich auf ein Implantat für eine Osteosynthesevorrichtung, insbesondere zur Wirbelsäulenkorrektur, gemäss der Gattung des Patentanspruchs 1.

Zur Behandlung von Wirbelsäulenverletzungen sind verschiedene Methoden und Osteosynthese-Vorrichtungen bekannt.

Aus der EP-Al 0 128 058 COTREL ist es bekannt Haken oder Schrauben in der posterioren Wirbelsäule zu verankern und mittels Längsträgern miteinander zu verbinden.

Aus der GB-A 2 173 104 WEBB ist eine Pedikelschraube mit geschlitzter, zur Aufnahme eines Längsträgers bestimmten Kopfpartie bekannt. Die Kopfpartie ist mit einem Aussengewinde versehen, so dass der in die geschlitzte Kopfpartie eingelegte Längsträger mittels einer Aufschraubkappe und einem zusätzlichen losen Einsatzelement festgeklemmt werden kann.

Aus der FR-A 2 624 720 COTREL ist ebenfalls eine Pedikelschraube mit geschlitzter, zur Aufnahme eines Längsträgers bestimmten Kopfpartie bekannt. Bei diesem Typ von Pedikelschraubenimplantat trägt die Kopfpartie ebenfalls ein Aussengewinde. Die Klemmung des Längsträgers erfolgt primär durch Auflage zweier diametral

gegenüberstehender Randpartien der Aufschraubkappe auf dem Längsträger. Die Aufschraubkappe weist überdies eine zentrale Bohrung auf, durch welche zusätzlich ein Dorn gegen den Längsträger eingeschraubt werden kann, so dass theoretisch eine Dreipunktauflage entsteht.

Schliesslich ist aus der EP-A1 0 348 272 LANOY eine zur FR-A 2.624.720 analoge Pedikelschraube bekannt, bei welcher die zweischenklige Kopfpartie jedoch ein Innengewinde trägt, in welches eine Madenschraube gegen den Längsträger eingeschraubt wird.

Bei allen aus dem Stand der Technik bekannten Systemen ist die Verbindung der Verankerungselemente (Haken oder Schrauben) mit dem Längsträger mit ernsthaften Problemen behaftet, welche weniger die mechanische Festigkeit der Verbindung, als vielmehr die intraoperative Handhabung der Verbindungsmechanismen durch den Chirurgen, ihre Adaptabilität, Zuverlässigkeit und ihren Platzbedarf betreffen.

Beim System gemäss der GB-A 2 173 104 WEBB ist ein zusätzliches loses Einsatzelement zur Klemmung des Längsträgers erforderlich, was dessen Handhabung kompliziert.

Beim System gemäss der EP-A1 0 348 272 LANOY sind die beiden Schenkel der Kopfpartie ungesichert und werden durch die Einführung der Madenschraube noch zusätzlich auseinandergespreizt.

Beim System gemäss der FR-A 2 624 720 COTREL besteht der Hauptnachteil darin, dass die Aufschraubkappe nicht selbsthemmend fixiert werden kann. Eine Lockerung der Verbindung mit dem Längsträger kann auch durch Einschrauben eines Dornes durch die Aufschraubkappe hindurch nicht verhindert werden. Im Gegenteil, durch die dadurch erzwungende Dreipunktauflage, kommt es zu einer Überbestimmung mit entsprechender Instabilität des Fixationssystems.

Ein weiterer Nachteil besteht in der ringförmigen Auflage der Aufschraubkappe auf dem Längsträger, welche bei diesem bekannten System resultiert. Eine solche Auflage ist insbesondere dann nachteilig, wenn der Längsträger - wie in den meisten Fällen üblich - gebogen ist. In diesen Fällen muss der Längsträger auf welche mindestens dem Durchmesser einer Strecke, der Aufschraubkappe entspricht, gerade ausgebildet sein. Wenn dieses Erfordernis nicht eingehalten wird, kann die Aufschraubkappe entweder nicht aufgeschraubt werden, oder es kommt bereits bei der kleinsten Biegung des Längsträgers zu einer einseitigen Verklemmung der Aufschraubkappe mit dem Längsträger. Diese einseitige Verklemmung ist ausserordentlich gefährlich, da die Aufschraubkappe, bei der geringsten Abkippung des Implantats (Pedikelschraube oder Haken) lose wird und den Längsträger frei qibt. Eine solche Abkippung des Implantats ist, bedingt durch die Belastung der Wirbelsäule durch den Patienten, nicht selten anzutreffen.

Schliesslich zeigt das System gemäss der FR-A 2 624 720 COTREL einen weiteren Nachteil bei dessen intraoperativer Handhabung, welcher darin besteht, dass das Aussengewinde, auf welches die Aufschraubkappe aufgeschraubt werden muss, durch die Schenkel

unterbrochen ist. Wird die Aufschraubkappe nicht absolut koaxial auf das Implantat aufgesetzt, so verkantet sie sich beim Aufschrauben. Eine solche Verkantung führt – bedingt durch das Erfordernis einer ringförmigen Auflage bei diesem System – wiederum zu einer unzureichenden Fixation, die vom Chirurgen, wegen der visuellen Beeinträchtigung des Wundzuganges, nicht wahrgenommen wird.

Hier will die Erfindung Abhilfe schaffen. Der Erfindung liegt die Aufgabe zugrunde ein Implantat für eine Osteosynthese-vorrichtung, insbesondere für die Wirbelsäulenkorrektur, zu schaffen, welche einfach in der Handhabung, sicher in der Anwendung und platzsparend ist.

Die Erfindung löst die gestellte Aufgabe mit einem Implantat, welches die Merkmale des Anspruchs 1 aufweist, sowie einer Verwendung des Implantats, welche die Merkmale des Anspruchs 7 aufweist.

Das erfindungsgemässe Implantat bewirkt durch die spezielle Konstruktion seines Klemmteils (Kappenteil mit koaxialer, äusserer Krempe zur Umschliessung der Schenkel und koaxialer, gewindeter Innenzylinder zum Einschrauben zwischen die Schenkel) eine Selbsthemmung des damit fixierten Längsträgers. Der Innenzylinder des Klemmteils spreizt beim Anziehen die beiden Schenkel geringfügig, wobei diese Spreizung gleichzeitig durch die äussere Krempe limitiert wird, was zu einer sicheren Verklemmung der Schenkel mit dem Klemmteil führt. Trotz kleinster Dimensionen kann damit das unkontrollierte Spreizen

oder Einfallen der Schenkel verhindert werden. Ein unbeabsichtigtes Lösen des Klemmteils und damit des Längsträgers wird damit ausgeschlossen.

Der beim erfindungsgemässen Implantat zentral liegende Klemmmechanismus, gestattet es den Klemmteil dank der Führungsfunktion seines koaxialen, gewindeten Innenzylinders ohne Verklemmungsgefahr in das Gewinde des Implantatkopfes einzuführen.

Insbesondere bei Verwendung des erfindungsgemässen Implantats mit einem gewindeten Längsträger kann der Chirurg die Deformationskorrektur in zwei Schritten der Wirbelsäule durchführen, was zu einer ausserordentlichen Vereinfachung des Eingriffs führt. In einer ersten Phase kann die Korrektur der Wirbelsäule in axialer Richtung durchgeführt werden (Distraktion oder Kompression). Ist dies geschehen, werden die einzelnen Fixationselemente (Pedikelschrauben oder Haken) provisorisch leicht fixiert. Durch dieses leichte Fixieren verkeilt sich das Gewinde des Längsträgers mit dem Kopfteil des Fixationswas zu einer 100%-igen Fixation elementes, erfindungsgemässen Implantats auf dem Längsträger in axialer Richtung führt. In einer zweiten Phase kann nun die Derotation durchgeführt werden. Bei diesem Arbeitsgang verhalten sich die provisorisch fixierten Fixationselemente wie Muttern auf einem Gewindestab, d.h. der Längsträger kann ohne grossen Kraftaufwand und sehr dosiert um seine Längsachse Verdreht werden, ohne dass die bereits vorgenommene axiale Korrektur der Wirbelsäule verändert wird. Nach erfolgter Derotation der Wirbelsäule können die einzelnen Fixationselemente definitiv fixiert werden.

Dieser Effekt kann noch zusätzlich verstärkt werden, indem man die Innenpartie des geschlitzten, zur Aufnahme des Längsträgers bestimmten Kopfteils des Implantats ebenfalls mit einem Gewinde versieht.

Anstelle von gewindeten Längsträgern und den damit zur Anlage kommenden gewindeten Innenpartien der Implantat-Kopfteile können auch quergerillte oder andersartig strukturierte Oberflächen verwendet werden.

Bei der bevorzugten Verwendung von strukturierten Oberflächen im erfindungsgemässen Implantat ergeben sich folgende zusätzliche Vorteile:

- Dank der Kombination von gewindeten oder quergerillten Längsträgern, mit gleichartig strukturierten Aufnahmen im Kopf des Implantats, kann eine optimale Verbindung der beiden Elemente erzielt werden;
- die sogenannte Derotation (Rotation des vorgebogenen Längsträgers) kann dank der Oberflächenstruktur der
   Verbindungselemente, unabhängig von der Distraktion oder Kompression vorgenommen werden;
  - die Haltekraft der erzielten Verbindung beschränkt sich nicht auf die Reibhaftung allein, sondern wird durch die Verhakung der Oberflächenstrukturen garantiert.

Bei einer bevorzugten Ausführungsform der Erfindung ist der Innenzylinder des Klemmteils an seinem freien Ende mit einer Spitze versehen um eine eindeutige punktuelle Fixation zu erzielen. Dank der zentrisch angebrachten Spitze können auch relativ stark gebogene Längsträger sicher fixiert werden. Anders als bei bekannten Implantatsystemen, welche ebenfalls über eine Spitze verfügen, hat die Spitze beim erfindungsgemässen Implantat nur die Funktion den - vorzugsweise strukturierten - Längsträger in die untere Partie des durch die beiden Schenkel gebildeten Kanals zu drücken. Dadurch wird die Pedikelschraube, bzw. der Haken axial am Längsträger fixiert. Die Rotation des Längsträgers im Pedikelschraubenkopf ist demgegenüber von geringerer Bedeutung, da pro Wirbelkörper zwei Pedikelschrauben eingebracht werden und zudem die beiden Längsträger sekundär miteinander verbunden sind.

Bei einer weiteren bevorzugten Ausführungsform bedeckt das Aussengewinde des Innenzylinders des Klemmteils nicht die so dass ein gewindeloser Frontteil gesamte Mantelfläche, resultiert. Die derart gebildete glatte Schulter entspricht im Innendurchmesser des Innengewindes Durchmesser dem Implantatkopfes. Die Länge der Schulter ist so zu wählen, dass sie beim Aufsetzen des Klemmteils, diesen zentriert und in der Gewindelängsachse führt. Ein Verkanten des Klemmteils beim Eindrehen kann dadurch verhindert werden. Diese Führungsfunktion ist bei allen Implantatsystemen mit unterbrochenem Gewinde, d.h. gespaltenem Implantatkopf, wozu auch das erfindungsgemässe Implantat gehört, von grosser Wichtigkeit.

Verschiedene Ausführungsbeispiele der Erfindung, welche zugleich deren Funktionsprinzip erläutern, sind in der Zeichnung dargestellt und werden im folgenden näher beschrieben.

Die Erfindung ist in den Figuren anhand von Ausführungsformen dargestellt, bei welchen der knochenseitige Teil des Implantats aus einer Pedikelschraube besteht. Es sind jedoch auch andere zur Verankerung mit dem Knochen, insbesondere mit den Wirbeln bestimmte Implantatteile für die Erfindung geeignet, beispielsweise in Form von Haken mit einem geschlitzten Kopfteil.

- Fig. 1 stellt einen axialen Längsschnitt durch den knochenseitigen Teil des erfindungsgemässen Implantats in Form einer Pedikelschraube dar;
- Fig. 2 stellt eine Aufsicht auf den Implantatteil gemäss Fig. 1 mit eingeführtem, aber noch nicht fixiertem Längsträger dar;
- Fig. 3 stellt einen axialen Längsschnitt durch den Klemmteil des erfindungsgemässen Implantats dar;
- Fig. 4 stellt eine seitliche Ansicht des Klemmteils nach Fig. 3 dar;
- Fig. 5 stellt einen Längsschnitt durch das erfindungsgemässe Implantats mit einem darin festgeklemmten Längsträger dar; und
- Fig. 6 stellt einen Längsschnitt durch das erfindungsgemässe Implantats nach Fig. 5 mit einem modifizierten Klemmteil dar.

Das in den Fig. 1 bis 4 in seinen Einzelelementen und in Fig. 5 gesamthaft dargestellte Implantat besteht im Wesentlichen aus einer Pedikelschraube 1 mit einem unteren, mit einem nicht dargestellten Schraubgewinde versehenen Teil 2 zur Knochenverankerung und einem oberen, als Schraubenkopf ausgebildeten Teil 3 zur lösbaren Fixierung mit einem Längsträger 4 und einem Klemmteil 5.

Der obere Teil 3 weist einen von vorn nach hinten verlaufenden, nach oben offenen Kanal 6 auf, der zwei seitliche Schenkel 7 zur Aufnahme des Längsträgers 4 bestimmt. Die zum unteren Teil 2 gewandte Partie 8 des Kanals 6 ist mit einer Strukturierung versehen, um die Verklemmung mit dem, ein Gewinde 18 aufweisenden Längsträger 4 zu verbessern. Die seitlichen Innenflanken 9 der Schenkel 7 sind mit einem Innengewinde 10 versehen.

Das in den Fig. 3 und 4 dargestellte Klemmteil 5 besteht im wesentlichen aus einem Kappenteil 11 mit Krempe 15 und einem einstückig damit verbundenen Innenzylinder 12, welcher an seiner äusseren Mantelfläche ein mit dem Innengewinde 10 des Schraubenkopfs 3 korrespondierendes Aussengewinde 13 trägt. An seinem freien Ende ist der Innenzylinder 12 zusätzlich mit einer Spitze 14 versehen. Der Klemmteil 5 weist eine zentrisch im Kappenteil 11 und im Innenzylinder 12 angebrachte Sechskantlochbohrung 20 auf, um das Einschrauben mittels eines geeigneten Instrumentes (Sechskantschlüssel) zu erlauben.

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Das Einsetzen des Implantats erfolgt in der Regel so, dass die Pedikelschraube 1 mit ihrem unteren als Schraubgewinde ausgebildeten Teil 2 im Knochen verankert wird und hierauf der Längsträger 4 - wie in Fig. 2 dargestellt - von oben zwischen die beiden ein Innengewinde 10 aufweisende Schenkel 7 des Pedikelschraubenkopfes 3 eingeführt wird.

Hierauf wird das in den Fig. 3 und 4 im Detail dargestellte Klemmteil 5 - wie in Fig. 5 - gezeigt auf den Pedikelschrauben-kopf 3 aufgesetzt. Der sich am freien Ende des Innenzylinders 12 befindliche, gewindelose Frontteil 19 weist einen Durchmesser auf, welcher dem Durchmesser des Innengewindes 10 entspricht und eine Länge, welche beim Aufsetzen des Klemmteils 5 dessen sichere Zentrierung garantiert, bis das Aussengewinde 13 des Innenzylinders 12 - in vollständig koaxialer Ausrichtung - mit dem Innengewinde 10 zum Eingriff kommt. Beim Einschrauben des Klemmteils 5 kommt schliesslich die Spitze 14 des Klemmteils 5 auf den Längsträger 4 zu liegen, wodurch dieser sowohl axial als auch rotativ festgeklemmt wird. Gleichzeitig sichert die Krempe 15 des Kappenteils 11 die beiden Schenkel 7 des Pedikelschraubenkopfes 3.

In Fig. 6 ist eine zweite Ausführungsform der Erfindung dargestellt, bei welcher der Klemmteil 5 - statt eines fest mit dem Kappenteil 11 verbundenen Innenzylinders mit Spitze - einen um die Implantatachse 16 drehbar gelagerten Kreiszylinder 17 mit konkav ausgebildeter freier Basisfläche 18 aufweist. Die Geometrie der Konkavität 18 entspricht zweckmässigerweise der

kreiszylindrischen Oberfläche des Längsträgers 4; im übrigen ist der Klemmteil 5 gleich gestaltet wie bei der Ausführungsform gemäss Fig. 5.

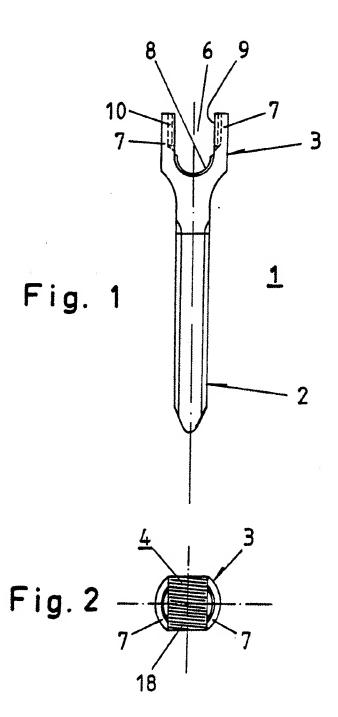
Beim Aufschrauben des solcherart modifizierten Klemmteils 5 kommt die konkav ausgebildete freie Basisfläche 18 des Kreiszylinders 17 auf die damit korrespondierende konvexe kreiszylindrische Mantelfläche des zwischen den Schenkeln 7 liegenden Längsträgers 4 zu liegen. In der letzten Phase des Aufschraubens wird der Kreiszylinder 17 rotativ blockiert, so dass sich nur noch der drehbar angeordnete Kappenteil 11 um die Implantatachse 16 bewegt. Ist der Klemmteil 5 vollständig aufgeschraubt, so resultiert eine über die gesamte Fläche der Basis 18 verteilte Fixationszone, was gegenüber der nur auf einen einzigen Punkt 14 beschränkten Fixation gemäss Fig. 5 eine ganz entscheidende Verbesserung bedeutet.

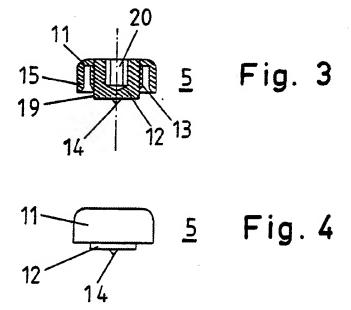
#### Patentansprüche

- 1. Implantat für eine Osteosynthesevorrichtung, insbesondere zur Wirbelsäulenkorrektur, mit einem unteren Teil (2) zur Knochenverankerung und einem oberen Teil (3) zur lösbaren Fixierung mit einem Längsträger (4), bei welchem der obere Teil (3) einen von vorn nach hinten verlaufenden, nach oben offenen Kanal (6) aufweist, der zwei seitliche Schenkel (7) Aufnahme des Längsträger (4) bestimmt, welche ein Innengewinde (10) aufweisen, dadurch gekennzeichnet, dass es einen Klemmteil (5) für den Längsträger (4) aufweist, der einen Kappenteil (11) mit koaxialer, äusserer Krempe (15) zur Umschliessung der Schenkel (7) und mit koaxialem Innenzylinder (12) zur Einführung zwischen die Schenkel (7) umfasst, wobei die äussere Mantelfläche des Innenzylinders (12) ein mit dem Innengewinde (10) des oberen Teils (3) korrespondierendes Aussengewinde (13) aufweist.
- 2. Implantat nach Anspruch 1, dadurch gekennzeichnet, dass die zum unteren Teil (2) gewandte Partie (8) des Kanals (6) mit einer Strukturierung versehen ist.
- 3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass der Innenzylinder (12) des Klemmteils (5) an seinem freien Ende mit einer, vorzugsweise zentrisch angeordneten Spitze (14) versehen ist.

- 4. Implantat nach einem der Ansprüche 1 3, dadurch gekennzeichnet, dass das Aussengewinde (13) des koaxialen
  Innenzylinder (12) nicht bis zu dessen freiem Ende verläuft,
  derart dass ein gewindeloser Frontteil (19) des Innenzylinders
  (12) resultiert.
- 5. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass der Innenzylinder (12) des Klemmteils (5) als um die Implantatachse (16) drehbar gelagerter Kreiszylinder (17) mit konkav ausgebildeter freier Basisfläche (18) ausgebildet ist.
- 6. Implantat nach Anspruch 5, dadurch gekennzeichnet, dass die konkave Oberfläche der Basisfläche (18) der kreiszylindrischen Oberfläche des Längsträgers (4) angepasst ist.
- 7. Verwendung des Implantats nach einem der Ansprüche 1 bis 6 zur lösbaren Fixierung eines Längsträgers (4), dadurch gekennzeichnet, dass der Längsträger (4) mit einem Gewinde (18) versehen ist.

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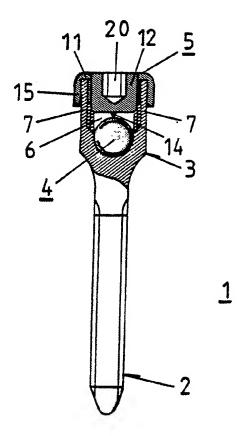


Fig. 5

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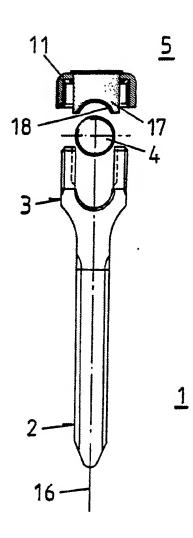


Fig. 6

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/CH 91/00174

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 4									
According to International Patent Classification (IPC) or to both National Classification and IPC									
Int. Cl. 5 A 61 B 17/60									
II. FIELDS	SEARCHED	Minimum Dazument	ration Searched 7						
	Minimum Documentation Searched 7  Classification System  Classification Symbols								
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	Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included In the Fields Searched								
III. DOCU	MENTS CONSIDERED	O BE RELEVANT							
Category *	Citation of Document	, 11 with Indication, where appr	opriate, of the relevant passages 12	Relevant to Claim No. 13					
х	FR,A,2 642 643 (VIGNAUD) 10 August 1990 1-4,7 see page 3, line 10 - line 13; figures 1,4								
A	US,A,2 439 99	2,4							
Α	EP,A, 0 318 39 see column 3,	1989 1; figure 3	2						
A	EP,A,O 328 883 see column 10	B(HOWMEDICA) 23 A , paragraph 2; fig	ugust 1989 gure 11	2,7					
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*Special categories of cited documents: 19  "A" document defining the general state of the art which is not considered to be of particular relevance  "E" earlier document but published on or after the international filing date  "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  "O" document referring to an oral disclosure, use, exhibition or other means  "P" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.  "A" document member of the same patent family  IV. CERTIFICATION									
Date of the Actual Completion of the International Search  Date of Mailing of this International Search Report									
Internation	18 November 1991 (18.11.91)         26 November 1991 (26.11.91)           International Searching Authority         Signature of Authorized Officer								
	FUROPEAN PATENT OFFICE								

## ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. CH 9100174 SA 4996 49965

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This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information, 18/11/91

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US-A-2439995		None		
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## ANHANG ZUM INTERNATIONALEN RECHERCHENBERICHT ÜBER DIE INTERNATIONALE PATENTANMELDUNG NR.

CH 9100174 SA 49965

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten internationalen Recherchenbericht angeführten Patentalokumente angegeben.
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Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	M	litglied(er) der Patentfamilie	Datum der Veröffentlichung
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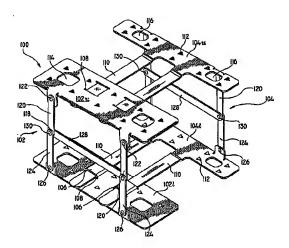
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : A61F 2/44	A1	(11) International Publication Number: WO 98/14142 (43) International Publication Date: 9 April 1998 (09.04.98)
(21) International Application Number: PCT/US (22) International Filing Date: 26 September 1997 (		CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL,
(30) Priority Data: 08/725,666 1 October 1996 (01.10.96)	τ	Published  With international search report.
(71) Applicant: SURGICAL DYNAMICS, INC. [US/I	US]; 1	11
(72) Inventors: LARSEN, Scott, W.; 18 Sugar Hill Road, N CT 06470 (US). SHIKHMAN, Oleg; 80 Camp Fic Fairfield, CT 06432 (US).		
(74) Agent: GERSHON, Neil, D.; United States Surgical tion, 150 Glover Avenue, Norwalk, CT 06856 (US	Corpor S).	ra-

(54) Title: SPINAL FUSION IMPLANT AND METHOD OF INSERTION THEREOF



#### (57) Abstract

A spinal fusion implant includes lower and upper plate members (1021, 1041, 102u, 104u) dimensioned for at least partial insertion within the intervertebral space defined between adjacent vertebrae. The lower and upper plate members (1021, 1041, 102u, 104u) have contacting surfaces (112) for engaging respective vertebral end faces of the adjacent vertebrae. A linkage mechanism (118) including at least one link member operatively connects the lower and upper plate members (1021, 1041, 102u, 104u). The linkage mechanism (118) is actually to cause relative movement of the lower and upper plate members (1021, 1041, 102u, 104u), wherein upon actuation, the contacting surfaces of the lower and upper plate members engage the vertebral end faces with the lower and upper plate members (1021, 1041, 102u, 104u) supporting the adjacent vertebrae in spaced relation during healing.

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#### SPINAL FUSION IMPLANT AND METHOD OF INSERTION THEREOF

## **BACKGROUND**

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## 1. Technical Field

The present disclosure relates generally to a surgical apparatus for fusing adjacent bone structures, and, more particularly, to an apparatus and method for fusing adjacent vertebrae.

## 2. Background of the Related Art

The fusion of adjacent bone structures is commonly performed to provide for long-term replacement to compensate for degenerative or deteriorated disorders in bone. For example, an intervertebral disc which is a ligamentous cushion disposed between adjacent vertebrae, may undergo deterioration as a result of injury, disease, tumor or other disorders. The disc shrinks or flattens leading to mechanical instability and painful disc translocations.

Conventional procedures for disc surgery include partial or total excision of the injured disc portion, e.g., discectomy, and replacement of the excised disc with biologically acceptable plugs or bone wedges. The plugs are driven between adjacent vertebrae to maintain normal intervertebral spacing and to achieve, over a period of time, bony fusion with the plug and opposed vertebrae. For example, U.S. Patent No. 4,887,020 to Vich discloses a cylindrical bone plug having a thread on its exterior, which is screwed into a correspondingly dimensioned cylindrical bore drilled in the intervertebral space.

Other devices and methods for intervertebral fusion are disclosed in U.S. Patent Nos. 4,863,477 to Monson; 4,874,389 to Downey; 4,932,969 to Fray et al;

5,306,307 to Senter et al; 5,306,308 to Gross et al.; and 5,401,269 to Buttner-Janz et al. The Monson '477 device discloses a synthetic intervertebral disc prosthesis molded in the same shape and general dimensions as a natural disc. The prosthesis includes two halves joined together to form a body having a fluid-tight cavity in its interior. The upper and lower surfaces of the disc each have a plurality of small suction cup-like projections molded thereon for frictionally engaging the adjacent vertebrae. The prosthesis is inserted within the intervertebral space and a volume of fluid is injected into the interior cavity of the prosthesis to create the necessary amount of resiliency which restores proper vertebral spacing.

More recently, emphasis has been placed on fusing bone structures (i.e., adjoining vertebrae) with prosthetic cage implants. One fusion cage implant is disclosed in commonly assigned U.S. Patent No. 5,026,373 to Ray et al.. The Ray '373 fusion cage includes a cylindrical cage body having a thread formed as part of its external surface and apertures extending through its wall which communicate with an internal cavity of the cage body. The fusion cage is inserted within a tapped bore or channel formed in the intervertebral space. The adjacent vertebral bone structures communicate through the apertures with bone growth inducing substances within the internal cavity to unite and eventually form a solid fusion of the adjacent vertebrae.

## 20 **SUMMARY**

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Accordingly, the present disclosure is directed to further improvements in the fusion of adjacent bone structures, e.g., adjacent vertebrae. In a preferred embodiment, an implant for insertion within an intervertebral space between adjacent vertebrae for supporting the vertebrae in predetermined spaced relation is disclosed. The implant includes lower and upper plate members dimensioned for at least partial insertion within the

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intervertebral space and having contacting surfaces for engaging respective vertebral end faces of the adjacent vertebrae. A linkage mechanism including at least one link member operatively connects the lower and upper plate members. The linkage mechanism is actuable to cause relative movement of the lower and upper plate members, wherein upon actuation, the contacting surfaces of the lower and upper plate members engage the vertebral end faces with the lower and upper plate members supporting the adjacent vertebrae in spaced relation during healing. The linkage mechanism is preferably adapted to cause lateral displacing movement of at least one plate member upon actuation thereof such that contacting surfaces of the lower and upper plate members are in general parallel relation when in the deployed position. Preferably, the contacting surfaces of the lower and upper plate members have discontinuities to engage the vertebral end plates. The discontinuities may be in the form of projections dimensioned for penetrating the vertebral end plates. The lower and upper plate members may further include at least one opening extending therethrough to permit bone ingrowth.

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In another preferred embodiment, an implant for insertion within the intervertebral space includes first and second plate members having engaging surfaces with discontinuities to engage vertebral end faces of the vertebrae, and at least one resilient member disposed between the first and second plate members to bias the first and second plate members to a generally open spaced arrangement. The one resilient member is configured and dimensioned to exert forces on the plate members sufficient to support the adjacent vertebrae in spaced relation during healing while permitting relative movement thereof to accommodate variations in loads realized during normal flexural movement of the vertebral column. Preferably, the one resilient member is a coil spring member. A plurality of coiled spring members may be incorporated as well.

In another preferred embodiment, an implant for insertion within the intervertebral space includes at least first and second supporting members dimensioned for insertion within the intervertebral space and having contacting surfaces for contacting vertebral end faces of the adjacent vertebrae. The first member has an inner arcuate articulating surface cooperating with a correspondingly dimensioned outer arcuate articulating surface of the second member to permit articulating movement of the first member so as to accommodate movement of the vertebral column during healing. Articulating surfaces of the first and second plate members each define a constant radius of curvature with the radius of curvature of each of the first and second plate members being substantially equal.

The contacting surfaces of the first and second plate members each include a plurality of apertures to permit bone ingrowth. A resilient member may be disposed between the first and second support members to facilitate the absorption of compressive forces.

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In yet another preferred embodiment, the implant includes at least first and second support members having engaging surfaces for engaging vertebral end plates of the vertebrae, and a camming arrangement having at least one camming member operatively engageable with the first and second support members. The camming member is moveable to move the first and second support members between a non-deployed position and a deployed position. The camming member includes a camming block having a camming surface which is engageable with a corresponding camming surface of at least one of the support members whereby, upon movement of the camming member, the camming surfaces interact to move the first and second support members between the non-deployed and the deployed positions. An actuating screw transverses a bore defined in the camming block and threadably engages a threaded bore associated with one of the first and second

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support members. The actuating screw is rotatable to cause corresponding movement of the camming block.

## BRIEF DESCRIPTION OF THE DRAWINGS

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Preferred embodiments of the disclosure are described hereinbelow with reference to the drawings wherein:

- FIG. 1 is a perspective view of a preferred embodiment of the implant for facilitating spinal fusion constructed in accordance with the principles of the present disclosure;
  - FIG. 2 is a perspective view with parts separated of the implant of FIG. 1;
    - FIG. 3 is a perspective view of the implant in a collapsed position;
- FIG. 4 is a view illustrating the implant in the collapsed position and inserted within an intervertebral space defined between adjacent vertebrae;
- FIG. 5 is an isolated view further depicting the implant positioned within the intervertebral space;
  - FIG. 6 is a view similar to the view of FIG. 5 illustrating the implant in its extended position supporting the adjacent vertebrae in spaced relation;
- FIG. 7 is a perspective view of an alternate embodiment of the implant of FIG. 1;
- FIG. 8 is a perspective view with parts separated of the implant of FIG. 7 illustrating the first and second support members, support springs disposed between the support members and a flexible cover surrounding the support spring;
  - FIG. 9 is a sectional view illustrating the implant positioned within the intervertebral space;

FIG. 10 is an isolated view illustrating a preferred arrangement for mounting the flexible cover about the support members;

- FIG. 11 is a view similar to the view of FIG. 9 illustrating the implant slightly compressed during normal flexural movement of the vertebral column;
- FIG. 12 is a perspective view of another alternate embodiment of the spinal implant;

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- FIGS. 13-14 are perspective view of the respective upper and lower support members of the implant of FIG. 12 illustrating the ball and socket arrangement for permitting relative articulating movement of the support members;
- FIG. 15 is a side plan view of the spinal implant of FIG. 12 in the assembled condition;
- FIG. 16 is a sectional view illustrating the implant positioned within the intervertebral space;
- FIG. 17 is a view similar to the view of FIG. 16 illustrating articulating movement of the upper support member via the ball and socket arrangement;
- FIG. 18 is a side plan view of an alternate embodiment of the spinal implant of FIG. 12 incorporating a resilient layer disposed between the upper and lower support member:
- FIG. 19 is a sectional view illustrating the implant of FIG. 18 positioned within the intervertebral space;
  - FIG. 20 is a view similar to the view of FIG. 19 illustrating articulating movement of the upper support member relative to the lower support member;
  - FIG. 21 is a perspective view of another alternate embodiment of the spinal implant;

FIG. 22 is a perspective view with parts separated of the implant of FIG. 21 illustrating the upper and lower support members, and the camming mechanism disposed between the support members for selectively moving the first and second support members between a retracted position and an extended position;

- FIG. 23 is a sectional view illustrating the implant in the retracted position positioned within the intervertebral space;
- FIG. 24 is a view similar to the view of FIG. 23 illustrating the implant in the extended position;
- FIG. 25 is a side plan view of another alternate embodiment of the spinal implant;
  - FIG. 26 is a cross-sectional view taken along the lines 26-26 of FIG. 25; and
  - FIGS. 27-28 are views similar to the view of FIG. 26 illustrating adjusting motion of the implant during flexural movement of the vertebral column.

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## **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)**

The apparatus of the present disclosure is intended for fusing adjacent bone structures and has particular application in the spinal fusion of adjacent vertebrae subsequent to a discectomy procedure. The apparatus may be implanted using any conventional surgical approach, e.g., anterior and/or posterior approaches, or may be implanted utilizing minimally invasive or endoscopic surgical techniques currently being utilized to carry out discectomy and spinal implant procedures.

Referring now to FIGS. 1-3, there is illustrated the apparatus constructed in accordance with the principles of the present disclosure. Apparatus 100 includes two separable support components 102, 104 which are adapted for adjusting sliding movement

relative to each other to selectively vary the overall width of the implant. Support component 102 has upper and lower support plates 102u,102l while support component 104 has upper and lower plates 104u, 104l. As shown, plates 102u, 102l of component 102 each have a greater width than plates 104u, 104l of component 104.

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Upper and lower plate portions 102u, 102l of support component 102 each include two raised portions 106 extending generally transversely therefrom which define longitudinal slots 108. Upper and lower plates 104u, 104l each have two transverse tongue portions 110 extending therefrom which are correspondingly dimensioned to be received within transverse slots 108 to mount support component 104 to support component 102. Tongue portions 110 are strategically dimensioned to slide within slots 108 thereby permitting selective adjusting movement of the component 104 relative to component 102. In this manner, the overall width of implant 100 may be varied to accommodate vertebral columns of various sizes or to increase or minimize the supporting capacity of the implant during healing. In particular, support components 102, 104 may be selectively moved toward each other via the tongue and slot arrangement to decrease the overall width of the implant 100 thereby permitting more lateral movement of the vertebral column during healing. On the other hand, support components 102, 104 may be moved away from each other to increase the overall width of the implant thereby providing a more stabilizing effect to the vertebral column.

Referring still to FIGS. 1-3, upper plate portions 102u, 104u and lower plate portions 102l, 104l each possess associated outer contacting surfaces which engage the vertebral end faces. The contacting surfaces define discontinuities to assist in engaging the vertebral end faces upon insertion within the intervertebral space. Preferably, the discontinuities are in the form of triangular-shaped projections 112 extending from the contacting surfaces, which define pointed edges to penetrate the vertebral end faces to

thereby resist tendency of the implant to move or become dislodged once positioned within the adjacent bone structures. Other discontinuities are envisioned as well such as knurling, bristle-coatings, etc... Upper plate portions 102u, 104u and lower plate portions 102l, 104l also include apertures 114, 116. Apertures 114, 116 permit bone ingrowth through their respective plates to facilitate fusion of the implant with the vertebral bodies.

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As best depicted in FIG. 1, linkage mechanism, identified generally by reference numeral 118, respectively operatively connects upper and lower plate portions 102u, 102l and upper and lower plate portions 104u, 104l. Each linkage mechanism 118 is preferably identical and includes transverse connecting links 120 connected to opposed ends of upper plate portions 102u, 104u through pins 122 and transverse connecting links 124 connected to opposed ends of lower plate portions 102l, 104l through pins 126. Connecting links 120, 124 are interconnected by longitudinal links 128 through pins 130. Each linkage mechanism 118 is moveable between the extended position shown in FIG. 1 where upper and lower plate portions are at their most displaced position and a collapsed position shown in FIG. 3.

Referring now to FIGS. 4-5, the implant 100 is shown positioned within the intervertebral space "i" defined between adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>". Implant 100 is typically inserted within the intervertebral space "i" subsequent to a discectomy procedure. Discectomy involves removal of a least a portion of the degenerated disc material with the use of the cutting instruments (not shown) e.g., scalpels, rongeurs, etc...

Prior to insertion, the width of implant 100 is adjusted by selectively adjusting the relative positioning of support components 102, 104 through the tongue and slot arrangement in the manner discussed above. Implant 100, in its collapsed condition, is thereafter positioned within the intervertebral space "i" with the use of a grasping instrument (not shown). As mentioned, conventional anterior or posterior approaches, as

well as laparosopic approaches, may be utilized. In the collapsed condition, implant 100 presents a reduced profile which facilitates its insertion. Once implant 100 is inserted and appropriately positioned, the linkage mechanisms 118 are actuated to displace upper plate portions 102u, 104u from lower plate portions 102l, 104l to move the implant to at least a partially extended position shown in FIG. 6. In this position, upper and lower plate portions 102u, 104u, 102l, 104l contact the vertebral end plates of the adjacent vertebrae in supporting engaged relation with triangular projections 112 of the plate portions penetrating the end plates to securely fix the implant member within the intervertebral space. In the deployed or extended position of FIG. 6, implant 100 forms a strut between adjacent vertebrae "V1 V2" supporting the vertebrae in desired spaced relation. Linkage mechanisms 118 sufficiently support components 102,104 in the extended position. It is envisioned that linkage mechanisms 118 may be locked in the deployed position by conventional arrangements such as with locking screws, etc... As shown, upper plate portions 102u, 104u are in general parallel relation with lower plate portions 102l, 104l. Over a period of time, the adjacent vertebral tissue communicates through apertures 114, 118 defined in the support components 102, 104 to form a solid fusion.

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It is envisioned that the interior cavity of implant 100 defined between the upper and lower plate portions may be packed with bone growth inducing substances as known in the art prior to insertion to facilitate the fusion process.

Referring now to FIGS. 7-8, there is illustrated an alternate embodiment of the spinal implant of the present disclosure. Implant 200 is intended to be used in a similar manner to that described in connection with implant 100 of FIG. 1, i.e., within the intervertebral space defined between adjacent vertebrae subsequent to a discectomy procedure. Implant 200 includes first and second plate members 202, 204 supported in spaced relation by a plurality of coiled support springs 206 which are disposed between the

plate members 202, 204. Springs 206 are received in correspondingly dimensioned impressions 208 defined in the inner surfaces of first and second plate members 202, 204 and extend in a generally transverse direction relative to each plate 202, 204 as shown. Support springs 206 permit deflecting movement, e.g., compressive movement of first and second plate members 202, 204 to permit flexural compressive movement of the vertebral column. Springs 206 are correspondingly dimensioned to provide sufficient force to withstand extreme compressive forces exerted by the spinal column.

As best depicted in FIGS. 8-9, first plate 202 includes a plurality (e.g., four) of transversely extending rigid tubular portions 210. Second plate 204 includes a plurality (e.g., four) of transversely extending rigid rod portions 212 extending from the inner surface thereof. Rod portions 212 are correspondingly dimensioned to be received within inner bores 214 defined by the tubular portions 210 to facilitate mounting of the first and second plate members 202, 204. In particular, the tubular portion 210 and rod portion 212 arrangement functions in preventing lateral movement of the first plate member 202 relative to the second plate member 204. The arrangement also serves in limiting the amount of compressive movement of plate members 202, 204 by engagement of the remote ends 210e of the tubular portions 210 with the inner surface of plate member 204. It is to be noted that tubular portions 210 are appropriately dimensioned to permit reciprocating movement of the rod portions 212 therein during compressive movement of the vertebral column.

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Referring to FIGS. 9-10, in conjunction with FIG. 8, a flexible cover 216 may be positioned about the periphery of implant 100 to enclose the coiled spring members 206. Cover 216 is preferably fabricated from a suitable biocompatible material. Cover 216 functions in preventing bone ingrowth from contacting the coiled support springs 206. Bone ingrowth within support spring 206 may potentially degrade the functioning of

springs 206. Cover 216 is preferably mounted to upper and lower plate members 202, 204 through a tongue and groove arrangement shown in detail in FIG. 10. Preferably, the outer ends of flexible cover 216 define a tongue 218 which is accommodated within corresponding recesses 220 formed in first and second plate members 202, 204.

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FIGS. 9 and 11 depict implant 100 positioned within the intervertebral space "i" defined between adjacent vertebrae " $V_1$   $V_2$ ". FIG. 9 illustrates implant 100 in a fully extended position corresponding to a minimal load exerted on the vertebral column. FIG. 11 illustrates implant 100 in a compressed condition when the vertebral column is subjected to a large compressive load with support springs 206 absorbing the load. In addition, in the inserted position of implant 200, pyramid-shaped projections 222 extending from the contacting surface 202, 204 penetrate the vertebral end plates of the " $V_1$ ,  $V_2$ " to facilitate mounting of the implant 200 within the intervertebral space "i", and to prevent the implant 200 from becoming dislodged prior to achieving full fusion with the adjacent vertebrae " $V_1$ ,  $V_2$ ".

Referring now to FIGS. 12-17 there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Spinal implant 300 includes first and second support members 302, 304 which supportingly engage adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>" upon insertion within an intervertebral space "i". Support member 302 includes a pair of parallel plates 306, 308 interconnected to each other through transverse side plate portions 312 and transverse intermediate plate portion 314. Similarly, second support member 304 includes a pair of parallel plate portions 316, 318 interconnected by side plate portions 320 and intermediate plate portion 322. First support member 302 and second support member 304 are preferably each integrally formed to form a single unit and may be fabricated from a ceramic material, a biocompatible metallic material or a biocompatible polymeric material. The respective upper and lower plate portions 306, 318 of first and

second support members 302, 304 have tissue contacting surfaces which define discontinuous surfaces to permit bone ingrowth during fusion. In a preferred embodiment, the discontinuous surfaces include a plurality of apertures 324 which permit bone ingrowth and a plurality of projections 326 which are disposed on a peripheral area of the respective plate portions. Projections 326 define penetrating tip portions which engage the vertebral end plate upon application within the intervertebral space.

Referring now to FIGS. 13-15, first and second support members 302, 304 are supported in general spaced relation by a ball and socket arrangement. In particular, first support member 302 has an integrally formed spherical portion 328 extending from lower plate 308. Second support member 304 has a projecting portion 330 extending from upper plate 316 and defining a generally spherical recess or socket 332 correspondingly dimensioned to accommodate spherical portion 328 of first support member 302. Spherical portion 328 is capable of articulating movement within socket 332 thereby permitting the vertebral column to flex through a generally "normal" range of motion. Preferably, spherical portion 328 and socket 332 define generally equivalent radii of curvatures.

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FIGS. 16 and 17 depict spinal implant 300 disposed within the intervertebral space "i" defined between adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>". As shown in FIG. 16, implant 300 supportingly contacts the upper and lower vertebrae "V<sub>1</sub>, V<sub>2</sub>" through the engagement of first support member 302 and second support member 304 with the vertebral end faces. Projections 326 extending from the upper and lower plate portions 316, 318 of first and second support members 302, 304 penetrate the vertebral end faces to assist in retaining the implant 300 within the intervertebral space "i" during healing.

FIG. 17 illustrates the articulating movement of the first support member 302 relative to the second support member 304 during movement of the spine. As shown, spherical portion 328 slides within socket 332 to permit such articulating movement.

FIGS. 18-20 depict an alternate embodiment of the spinal implant 300 of FIGS. 12-17. This embodiment is similar in most respects to the implant 300, but, further incorporates a resilient layer 350 disposed between first and second support members 302, 304. Resilient layer 350 is preferably a sponge like material and serves to provide a cushion between first and second support members 302, 304 and the adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>" to accommodate compressive forces realized by the vertebral column during movement as depicted in FIG. 20.

Referring now to FIGS. 21-24, there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Implant 400 includes two support members, i.e., upper support member 402 and lower support member 404 having respective contacting surfaces 406, 408. Each contacting surface 406, 408 has a plurality of pyramid-shaped projections 410 which facilitate engagement with the vertebral end plates of the adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>" upon insertion within the intervertebral space "i". Implant 400 further includes a camming arrangement for moving upper and lower support members 402, 404 between an open and a closed position. The preferred camming arrangement includes a camming block 412 which is adapted for traversing movement within the interior of implant 400. Camming block 412 defines an inclined camming surface 414 which engages a correspondingly dimensioned inner surface 416 of support member 402. The camming arrangement further includes a threaded element, e.g., screw 418, which traverses a bore 420 within camming block 412 and threadably engages an internal threaded bore 422 of lower support member 404.

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Support members 402, 404 are interconnected through a pin and slot arrangement. More particularly, support member 402 has a pair of transversely extending slots 424 formed in side plates 426. Support member 404 has a pair of correspondingly positioned apertures 428 formed in side plates 430. A pin 432 traverses each slot and

opening arrangement to connect upper support member 402 and lower support member 404.

FIGS. 23-24 illustrate rotational movement of screw 418 and the consequent corresponding traversing movement of camming block 412. In particular, rotation of screw 418 in a clockwise direction causes the screw to advance within threaded bore 422 thereby advancing camming block 412 in the direction indicated by the directional arrow in FIG. 24 and displacing upper support member 402 from lower support member 404. As upper support member 402 moves relative to lower support member 404, pins 432 traverse slots 424 of upper support member 402.

Referring now to FIGS. 25-28, another alternate embodiment of the present disclosure is illustrated. Implant 500 includes upper and lower support members 502, 504 and at a resilient layer 506 disposed between the support members 502, 504. Each support member 502, 504 includes first and second plate members 508, 510. First and second plate members 508, 510 are interconnected by peripheral interconnecting members 512, 514 and intermediate interconnecting member 516. An internal cavity 518 is defined between the plate members 508, 510. Support members 502, 504 are each preferably integrally formed to form a single component as shown.

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First plate member 508 has a plurality of apertures 520 extending therethrough in communication with internal cavity 518 to promote bone ingrowth to facilitate the fusion process. A plurality of triangular-shaped projections 522 or teeth extend from the first plate member 508 and are dimensioned to penetrate the vertebral end faces to facilitate retention of the implant 500 within the intervertebral space. First plate member 510 of support member 504 is preferably inclined relative to axis "a" of the implant. This inclined configuration provides.

Resilient layer 506 disposed between plate members 508, 510 is preferably formed of a resilient material such as synthetic rubber or other elastomeric material. Resilient layer 506 provides sufficient forces to maintain the adjacent vertebrae in spaced relation while permitting relative flexural compressive movement of the vertebral column as depicted in FIGS. 27-28. Alternately, instead of resilient layer 506, compression springs, covered by a flexible film so as not to interfere with surrounding tissue, could be positioned between the upper and lower support member. Parallel pins to provide shear strength can be positioned adjacent the springs spanning the space between the upper and lower supports.

While the above description contains many specifics, these specifics should not be construed as limitations on the scope of the disclosure, but merely as exemplifications of preferred embodiments thereof. Those skilled in the art will envision many other possible variations that are within the scope and spirit of the disclosure as defined by the claims appended hereto.

## WHAT IS CLAIMED IS:

1. An implant for insertion within an intervertebral space between adjacent vertebrae for supporting the vertebrae in predetermined spaced relation, which comprises:

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lower and upper plate members dimensioned for at least partial insertion within the intervertebral space defined between adjacent vertebrae, the lower and upper plate members having contacting surfaces for engaging respective vertebral end faces of the adjacent vertebrae; and

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a linkage mechanism including at least one link member operatively connecting the lower and upper plate members, the linkage mechanism actuable to cause relative movement of the lower and upper plate members, wherein upon actuation, the contacting surfaces of the lower and upper plate members engage the vertebral end faces with the lower and upper plate members supporting the adjacent vertebrae in spaced relation during healing.

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2. The prosthetic implant according to claim 1 wherein the linkage mechanism is adapted to cause lateral displacing movement of at least one plate member upon actuation thereof such that the contacting surfaces of the lower and upper plate members are in general parallel relation when in the deployed position.

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3. The prosthetic implant according to claim 2 wherein the contacting surfaces of the lower and upper plate members have discontinuities to engage the vertebral end plates.

4. The prosthetic implant according to claim 3 wherein the discontinuities are projections dimensioned for penetrating the vertebral end plates.

- The prosthetic implant according to claim 3 wherein the lower and
   upper plate members each include at least one opening extending therethrough to permit bone ingrowth.
- The prosthetic implant according to claim 1 wherein each of the lower and upper plate members include first and second plate portions, the first and second
   plate portions being relatively moveable such that the width of each plate member is selectively adjustable.
  - 7. The prosthetic implant according to claim 6 including two linkage mechanisms, a first of the linkage mechanisms interconnecting the first plate portions of the lower and upper support members, a second of the linkage mechanisms interconnecting the second plate portions of the first and second support members.

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- 8. The prosthetic implant according to claim 7 wherein the first and second plate portions are connected through a tongue and slot arrangement, the tongue and slot arrangement adjustable to permit relative movement of the first and second plate portions.
- 9. An implant for insertion within an intervertebral space between adjacent vertebrae for supporting the vertebrae in spaced relation during healing, which comprises an implant member including first and second support components, the support

components being operatively connected and moveable relative to each other to selectively adjust the effective width of the implant member, each support component including upper and lower plate portions with contacting surfaces for engaging respective vertebral end faces of the adjacent vertebrae.

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- between adjacent vertebrae, comprising first and second plate members dimensioned for insertion within the intervertebral space, the first and second plate members having engaging surfaces with discontinuities to engage vertebral end faces of the vertebrae, and at least one resilient member disposed between the first and second plate members to bias the first and second plate members to a generally open spaced arrangement, the one resilient member configured and dimensioned to exert forces on the plate members sufficient to support the adjacent vertebrae in spaced relation during healing while permitting relative movement thereof to accommodate variations in loads realized during normal flexural movement of the vertebral column.
- 11. The implant according to claim 10 wherein the resilient member is a coil spring member.
- 12. The implant according to claim 11 including a plurality of coiled spring members disposed between the plate members.
  - 13. The implant according to claim 12 including a flexible cover surrounding the spring members to prevent bone ingrowth within the spring members.

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14. The implant according to claim 10 wherein the resilient member includes a resilient layer.

- 15. An implant for insertion within an intervertebral space defined between adjacent vertebrae for supporting the vertebrae in predetermined spaced relation during healing which comprises at least first and second supporting members dimensioned for insertion within the intervertebral space and having contacting surfaces for contacting vertebral end faces of the adjacent vertebrae, the first member having an inner arcuate articulating surface cooperating with a correspondingly dimensioned outer arcuate articulating surface of the second member to permit articulating movement of the first member to accommodate movement of the vertebral column during healing.
- The implant according to claim 15 wherein the contacting surfaces of the first and second plate members each include a plurality of apertures to permit bone
   ingrowth.
  - 17. The implant according to claim 15 wherein the articulating surfaces of the first and second plate members each define a constant radius of curvature, the radius of curvature of each of the first and second plate members being substantially equal.

- 18. The implant according to claim 15 further including a resilient member disposed between the first and second support members.
- 19. The implant according to claim 18 wherein the resilient member25 includes a layer of sponge-like material.

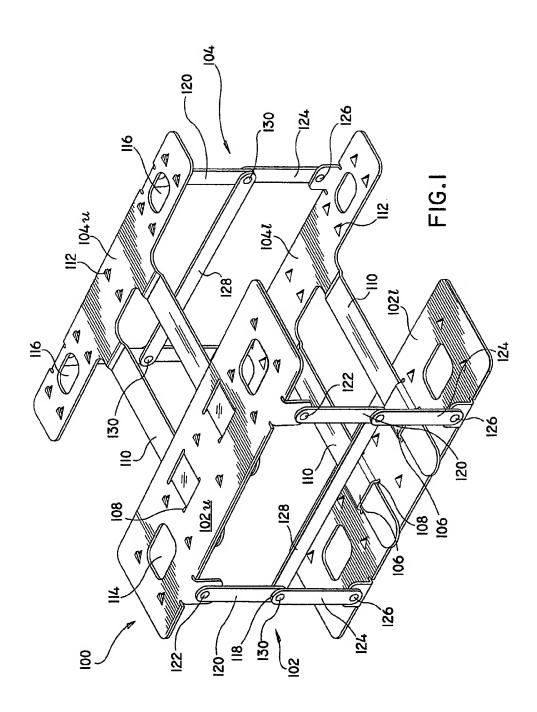
20. An implant for insertion within an intervertebral space defined between adjacent vertebrae for supporting the vertebrae in predetermined spaced relation during healing, which comprises at least first and second support members dimensioned for insertion within the intervertebral space defined between adjacent vertebrae and having engaging surfaces for engaging vertebral end plates of the vertebrae, and a camming arrangement having at least one camming member operatively engageable with the first and second support members, the camming member moveable to move the first and second support members between a non-deployed position and a deployed position.

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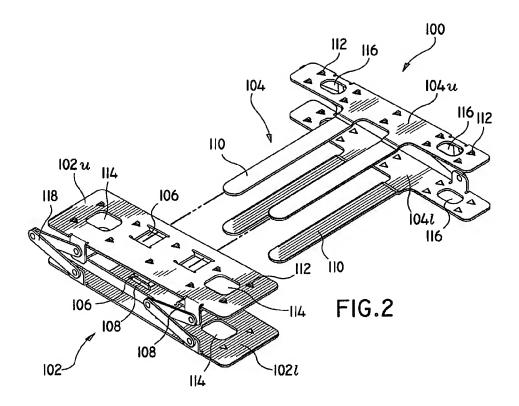
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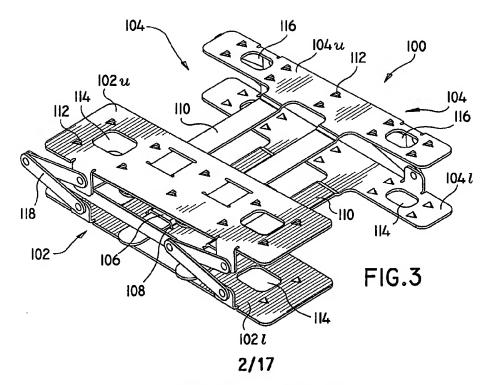
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- 21. The implant according to claim 20 wherein the camming member includes a camming block having a camming surface, the camming surface engageable with a corresponding camming surface of at least one of the support members whereby upon movement of the camming member the camming surfaces interact to move the first and second support members between the non-deployed and the deployed positions.
- 22. The implant according to claim 21 including an actuating screw transversing a bore defined in the camming block and threadably engaging a threaded bore associated with one of the first and second support members, the actuating screw rotatable to cause corresponding movement of the camming block.

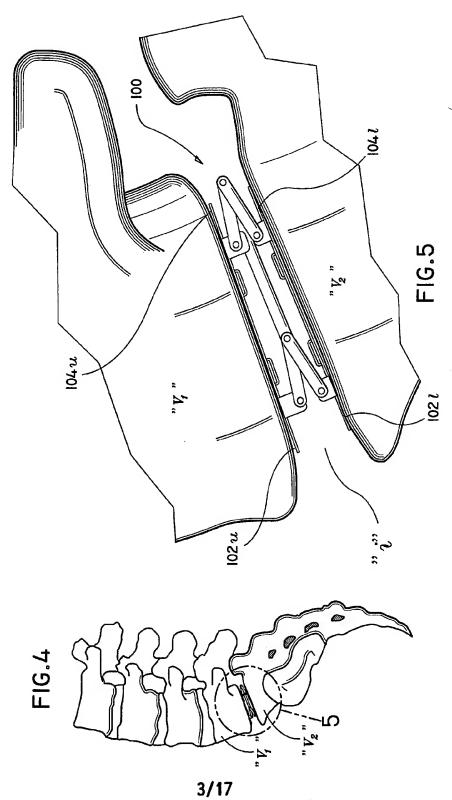


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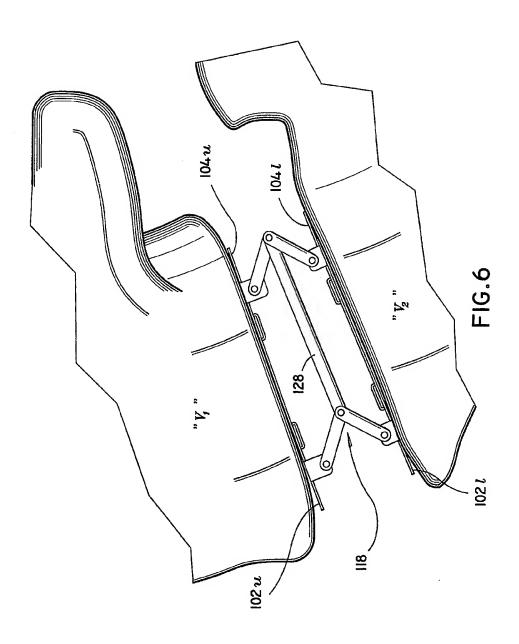




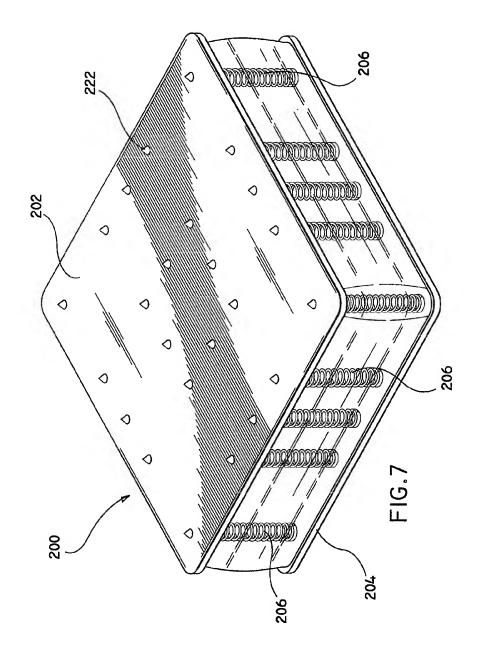
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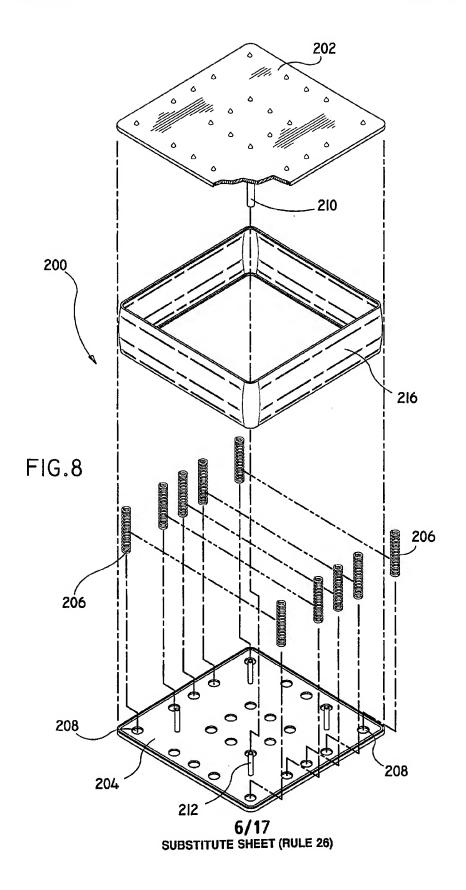
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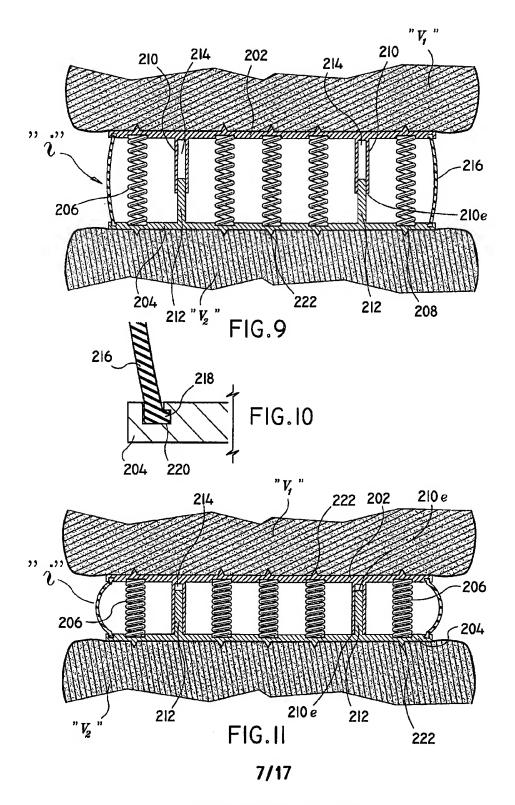


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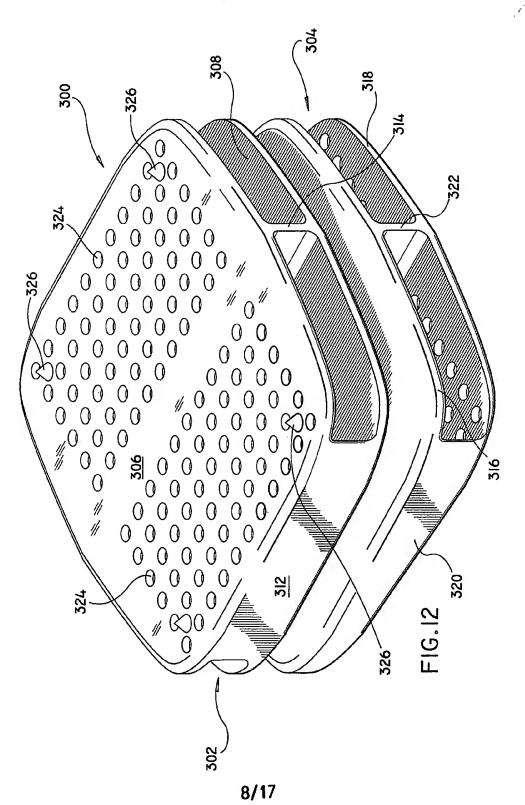


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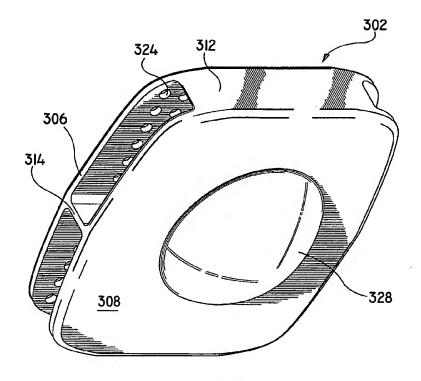
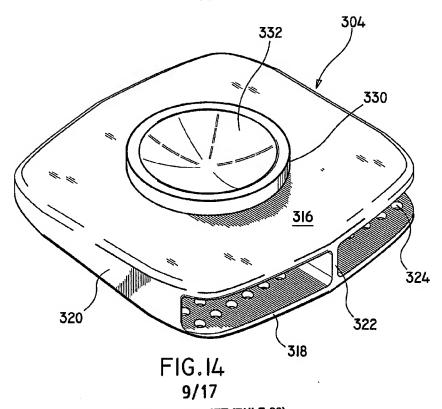
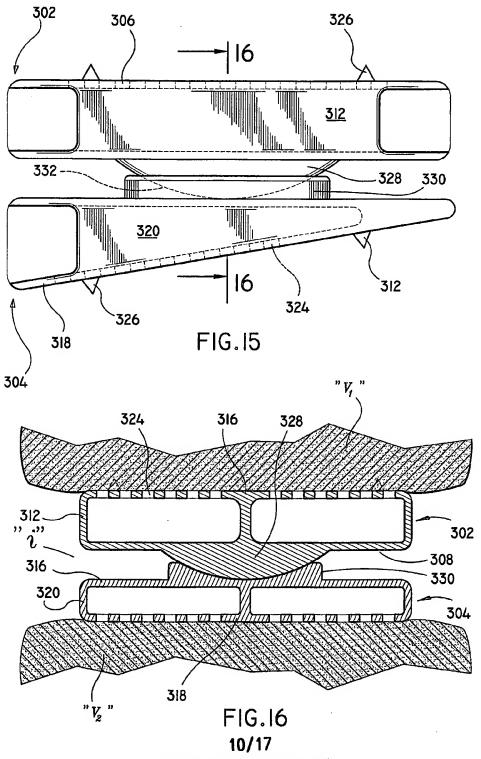


FIG.13



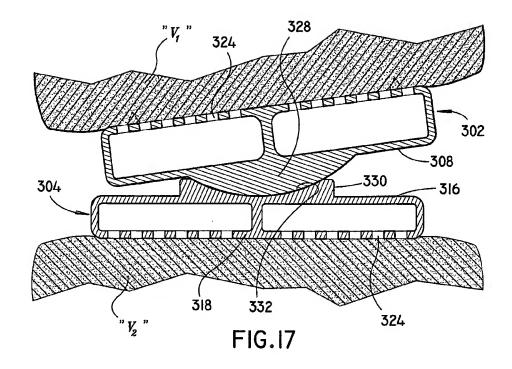
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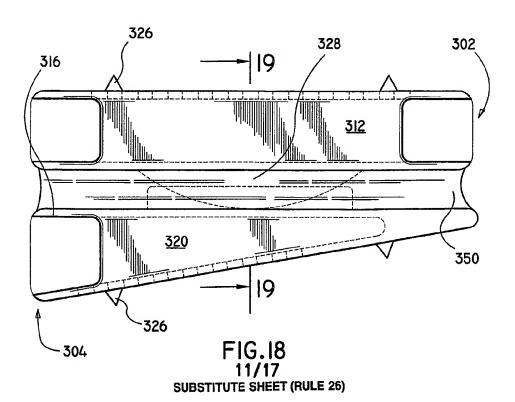
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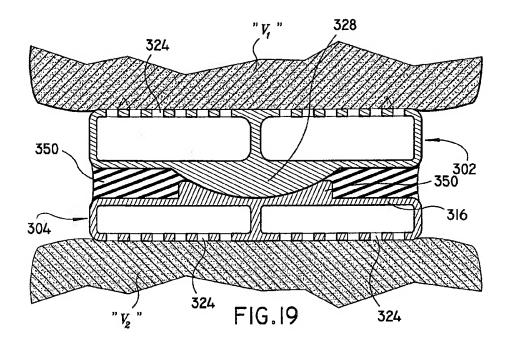
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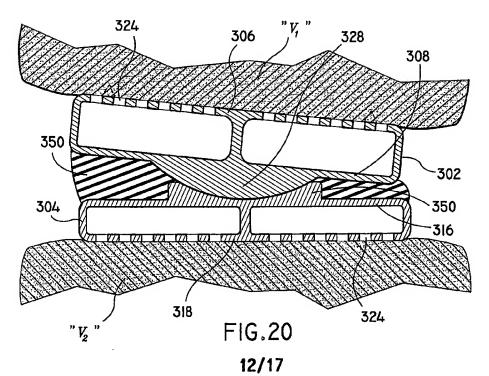
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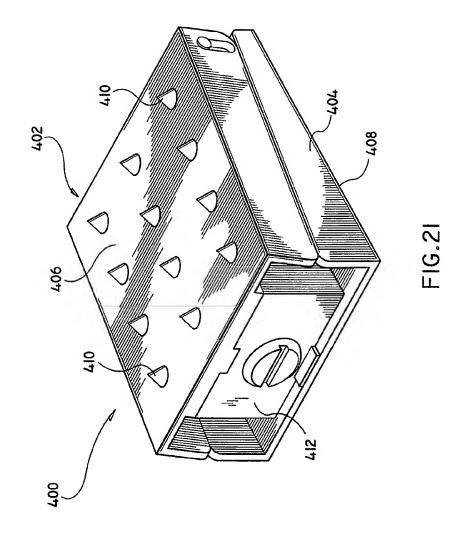


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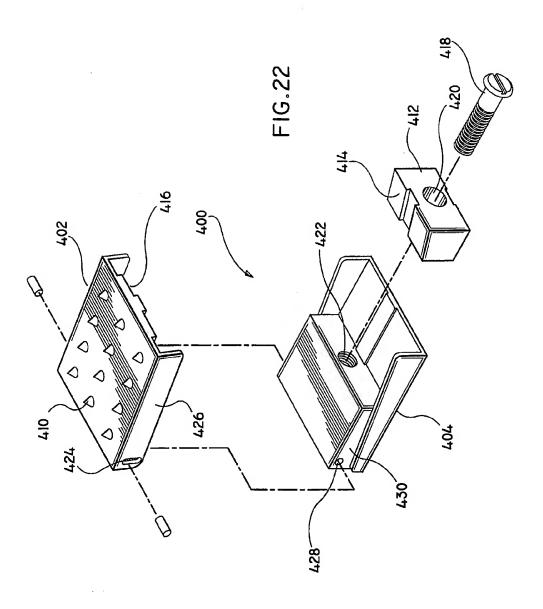




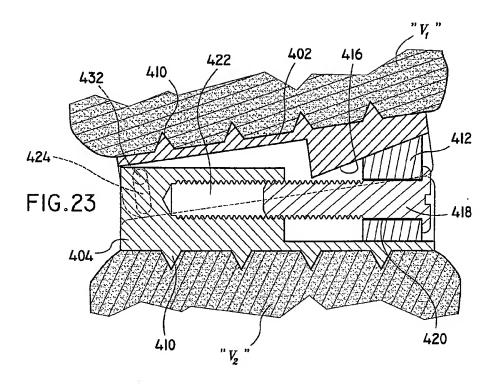
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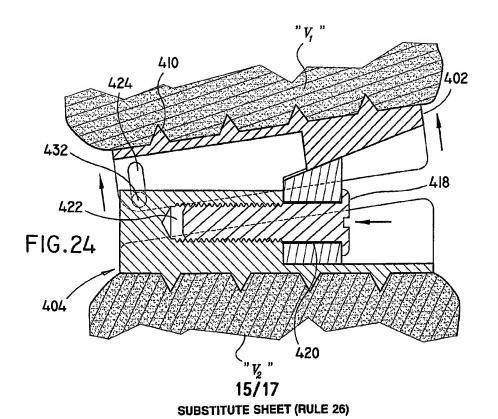


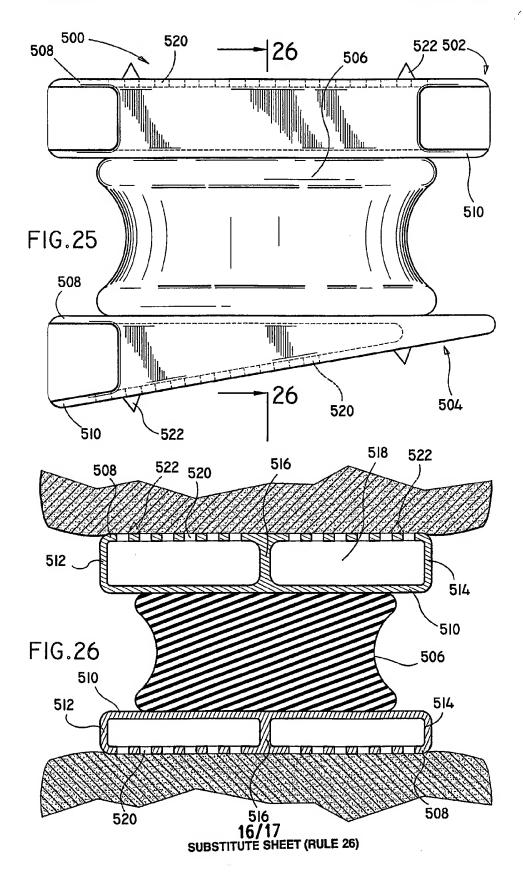
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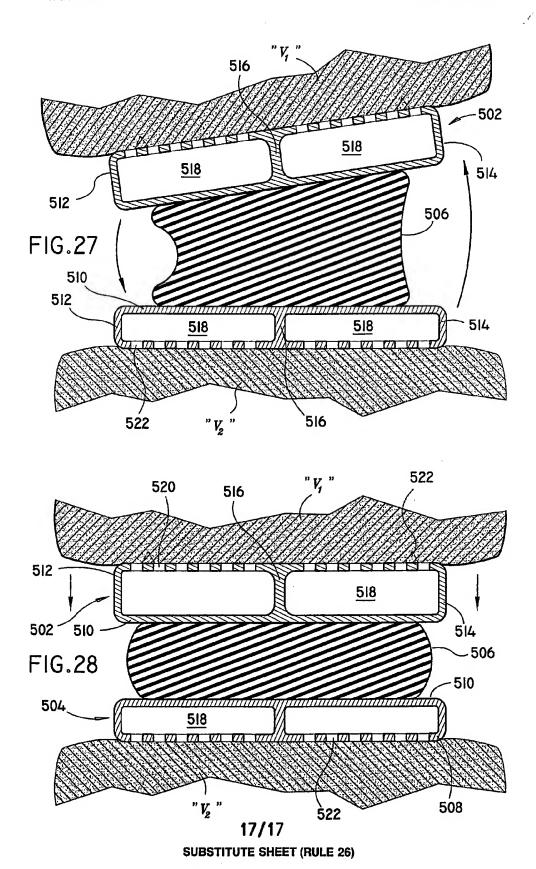


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# INTERNATIONAL SEARCH REPORT

International application No. PCT/US97/17383

A. CLASSIFICATION OF SUBJECT MATTER	
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According to International Patent Classification (IPC) or to both national classification and IPC	
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U.S. : 623/17; 606/61	
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X,P US 5,665,122 A (KAMBIN) 09 September 1997, Fig. 9.	9, 20, 21
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WO 94/04100 A (MAZDA) 03 March 1994, Fig. 3.	15, 17-19
Y	16
X,P US 5,609,635 A (MICHELSON) 11 March 1997, Figs. 1, 8	, 20-22
Y,P 30, and 31.	16
X Further documents are listed in the continuation of Box C. See patent family annex.	
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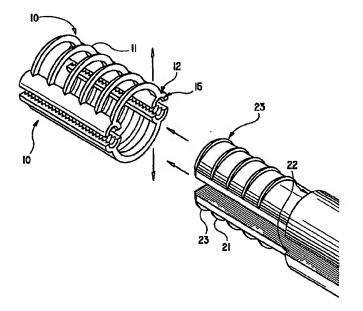
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#### Published

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(54) Title: EXPANDABLE NON-THREADED SPINAL FUSION DEVICE



#### (57) Abstract

An apparatus for facilitating the fusion of adjacent bone structures includes implant members (4) configured for insertion within a space defined between adjacent bone structures. The device of the disclosure provides a series of resilient supporting arches (11) which serve to act as spacers between two adjacent bone structures. The implant members (4) include a longitudinal portion separated by a plurality of ribs and a lateral chamber used to accommodate various sized spacer rods (16, 17, 18).

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# EXPANDABLE NON-THREADED SPINAL FUSION DEVICE

## **BACKGROUND**

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#### 1. Technical Field

The present disclosure generally relates to a surgical apparatus and associated methods for fusing two adjacent bone structures such as vertebrae of the spine using an anterior or posterior interbody approach.

## 2. Background of the Related Art

The deterioration of a body joint such as an intervertebral disc causes the joint space to undergo degenerative changes including narrowing of the joint space and stiffening of the joint. This degeneration of the joint space may lead to mechanical instability of the joint and become severely painful. When no other alternative treatment suffices to stop the disabling pain the joint may have to be fused together.

The fusion process for intervertebral discs typically requires surgically altering the joint surfaces with removal of the articular cartilage and internal tissues attached to the bone. A mechanical device and/or bone material is inserted into the joint to cause the two formerly moving surfaces to fuse or bridge together via the inserted device or bone. Due to various natural effects, bone fusions grow slowly. As such, the bony union may require a period of several weeks or months of bone ingrowth to have sufficient strength to support normal joint loading. The healing period is of course dependent upon such factors as the patient's age, the location of the joint, the forces applied to the joint and the rate

by which the bony union progresses in the particular patient. A successful fusion demands that the bone structure of the one bony component of the joint grow together with the bone structure of the second bony component of the joint thereby creating a solid union between these two bony components.

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All bones are composed of cortical and cancellous portions, the cortical portion being a thin, hard outer shell and the cancellous portion including an internally soft material. It is known that the most successful fusion promoting substance to be inserted between the two joint components is cancellous or soft bone taken as a graft from a donor site within the patient's body. This soft bone constitutes an autograft and contains growth promoting substances and biochemical materials which accelerate the rate of growth and quality or solidity of the resultant bone fusion. Further, the bone graft material must be supported and stabilized so that it is not subjected to motion or dislocation. During the growth of the bone fusion, a space less than  $200\mu M$  between the bone components and the fusion material will inhibit good bone growth. However, a space of this size or larger permits the ingrowth of fibrous tissue causing the resulting fusion to be poor in strength or to fail to fuse altogether. Along the same lines, motion within the fusing joint or between the bone graft particles will also inhibit bone growth and subsequently inhibit a secure attachment of the bone graft particles to the joint's bony components. In addition, the bone graft material must be brought into contact with a bleeding or vascularized surface of the bone joint to be fused. Since the cancellous inner bone has good intrinsic circulation which is vital to fusion growth, the outer cortical bone must be cut or ground away such that the vascularized cancellous inner bone is exposed and bleeding. It is to this bleeding

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or vascularized surface that the bone graft is applied.

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Proper bone fusion requires that the bone graft material be held firmly in place within the joint space without any excess movement throughout the fusion process. Many methods and devices have been devised to secure the bonc graft firmly in place as well as to secure the bony components of the joint in the desired position as the bony fusion slowly develops. Conventional prior art fusion devices are not suitable for the requirements for which the disclosure has been developed. For example, U.S. Patent No. 4,961,740 to Ray et al. discloses an interbody cage having an internal cavity with an inner surface and an outer surface. A pair of these devices is screwed into parallel round cavities drilled into the adjacent end plates of the vertebral disk bodies. These cavities traverse the end plates of each vertebra penetrating into their cancellous bony vertebral substance. The cavities are then tapped and tight fitting metal cages are screwed into the cavities. The cages hold the bone graft and the vertebral bodies firmly in place. Perforations that face the vertebrae are abundant, up to 70% of the outer surface, but the lateral sides of the cages that face the disc space interposed between the vertebrae are blocked against possible soft tissue ingrowth. Such circular fusion devices must penetrate through the cartilaginous vertebral end plate and into the spongy bone of the vertebral body in order for the bone graft material to grow into the vertebral body and create a solid fusion.

The physical shape, namely the height, of a degenerative vertebral disk is dependent upon its actual state of degeneration. In the less degenerated disc, the diameter of the circular fusion cage must be increased to conform with the disk shape. The maximum diameter of a single cage that can be accepted in a

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given disc joint is limited by the space between the facet joint or pedicle, laterally, and the posterior disc midline. Thus, there is a limit to which the cage can effectively span the disc in relation to the disk height required and the disk posterior width available. The fusion device of the disclosure allows for an increase in height without a resulting concomitant increase in width.

For successful fusion growth development, the recipient bone surfaces must have the cortical or hard surface portion removed. Beneath this hard surface, the cancellous or soft inner portion of the bone, containing its own circulation will then be exposed to the placement of fusion inducing substances such as cancellous or soft bone from another human (allograft) or from the same patient (autograft). When these fusion inducing substances are first placed within the recipient bone, they have little cohesive strength and therefore are very soft and loosely packed. Therefore, a number of devices and appliances have been developed to hold the bony segments in place under conditions of normal spinal activity and daily stresses. The bone graft material being placed between these segments will slowly reunite the segments. Such devices are not, by themselves, intended to permanently secure immobility of the segments, since bone ingrowth is required to produce the stable fusion.

Dependency on any non-uniting device as the sole stabilizing element may ultimately fail due to the development of mechanical transitions between the bone and the device which will lead to a structural failure of the bone.

Fusion bone material placed between vertebral bodies has been described for some years, but more recently the development of pedicle screw fixation and posterolateral instrumentation has become increasingly popular

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because of the improvement in percentage fusion rate as compared to the earlier interbody fusion methods. However, the pedicle screw technique has been fraught with a number of problems, particularly related to the patient's safety. Most recently, interbody fusion methods utilizing a bone container, such as a threaded fusion cage, have become increasingly popular because of the improvement in safety and efficacy over other methods and because of lower incidences of complications.

The interbody fusion method is known to be a more efficient technique as compared to methods where bone material is placed around the outside of the vertebral bodies. The interbody fusion is at the center of motion of the spinal segment and requires the least volume of bone to effect a good bone fusion. Further, the fusion enhancing bone material is nearly surrounded by the cortical and/or cancellous bone of the vertebrae which provides good nutrition for the fusion growth. For bone material which is laterally placed, nutrition is usually derived from the under surface of the surrounding muscle which is vascularized during the insertion of the fusion device.

The use of cylindrical interbody fusion devices are simpler and safer to implant than are rectangular bone grafts or fusion enhancing devices. To implant a pair of threaded cylindrical fusion devices by a posterior approach, the disc space is entered via two parallel penetrations, one on either side of the central spinous process. Two holes are then drilled or tapped into the interposed disc space and into the adjacent surfaces of the vertebral bones so as to accommodate the two parallel hollow cages. In the case of implanting a pair of threaded cylindrical fusion devices by an anterior approach, two holes are drilled or tapped

in close proximity. Screw threads are then cut into the recipient bone bed. The screw threads penetrate into each of the vertebral bodies by a distance of about 3 mm which is sufficient to permit direct contact with vascularized cancellous portions of the vertebrae.

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The implantation of a pair of fusion devices is important for stability of the joint space but the method for inserting them must abide by certain anatomical limitations. For example, a singular implant of large diameter of more than 18 to 20 mm cannot be implanted by a posterior approach since the nerves cannot be retracted far enough from either side of the midline to permit such a large device to be safely inserted. The excessive nerve retraction required could readily lead to a nerve stretch injury with damage to nerve function resulting in postoperative severe pain or partial paralysis. Although a range of diameters of the inserts must be available to accommodate disc spaces of different height, fortunately, it has been found that only two different lengths (21 mm and 26 mm) of the implants are needed to accommodate the normal range of vertebral sizes.

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The height of the disc space determines the diameter of the insert to be implanted. The distance between the pedicles, from side-to-side across the disc space of the vertebral body ranges from about 30 mm to 45 mm in different sized patients. This distance limits the transverse space available to one or more implants. However, the entire width between the pedicles cannot be used since the vertebrae are oval shaped and the corners of the implants cannot extend outside the vertebral body oval. To do so would otherwise damage or endanger important nerves or major blood vessels that closely approximate the vertebrae. Thus, the combined diameters of a pair of implant devices cannot be wider than about 6 mm

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less than the overall vertebral body width along the disc level. Therefore, the available practical width usable for a pair of cylindrical implants ranges from about 24 mm to 39 mm. Since each cylindrical implant device must penetrate about 3 mm into each vertebral body so as to contact the cancellous portion of the bone, a disc height equaling or exceeding about 12 mm would require each cylindrical device to be about 18 mm to 20 mm in diameter. However, a pair of such sized devices cannot physically be accepted into a side-to-side arrangement width of the intervertebral disc space. As such, a transversely narrow vertebral segment having a high disc degradation space cannot accommodate two parallel cylindrical implants. Clearly, an improved implant having the ability to increase vertical height without the associated increase in width is needed in the art.

In order for an interbody fusion device to be stable once implanted within the disc space, it is necessary that the device and its implantation technique stretch the anulus fibrosus, the ligamentous band surrounding the outer portion of the disc. The effective elastic recoil effect of this tough ligament plus the patient's body weight and paravertebral muscle tone, collectively, apply considerable force from both vertebral bodies through the implanted fusion implant, thereby stabilizing the device within the intervertebral space. Further, a pair of such cylindrical implants parallelly placed into the disc space provides important segmental stability as the bone fusion grows. This stability must withstand normal lateral flexion-extension and torsional forces applied to the segment. A singular cylindrical implant may provide considerable torsional and flexion-extension stability when implanted parallel to the front-back axis of the disc space, but would not provide adequate stability in lateral side-to-side bending as the segment

would hinge over the implant.

The collapse of an implanted cylinder is prevented by two mechanisms, first, the arc of the cage pressing into the vertebral bone includes a distinct compression strength. Secondly, the greater diameter of the implanted cylindrical fusion device is wider than the hole bored into the two vertebrae, that is, the maximum width of the device lies in the disc space inside the vertebral end plates. Therefore, for such a device to further penetrate into either end plate it must stretch the end plate cortical bone. This portion of the cortical bone is the strongest portion of the vertebral body and resists such stretching forces. In actual clinical applications, the implant cages have penetrated into the vertebral bodies by less than 1 mm. The intactness of the cortical edge of the end plate is therefore important to prevention of the collapse of the vertebrae around the implants. A substantial loss in disc space height would be detrimental to the posterior ancillary structures of the spinal segment including the anulus, facet joints and ligaments.

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A spherical, expandable spinal implant is disclosed in U.S. Patent No. 5,059,193 to Kuslich. The Kuslich implant includes deformable ribs which may be expanded outwardly once installed inside the prepared disc space. As a spherical implant, however, it is inherently unstable as was ball bearing type implants disclosed by U. Fernstrom in 1966. The Fernstrom device, intended as an artificial disc, proved to be a non-functional device and most of the several hundred devices implanted had to be later removed.

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A spine fusion implant having an oval contour is disclosed in U.S. Patent Nos. 5,458,638 and 5,489,308 to Kuslich et al. The Kuslich et al. implants include slots along its outer periphery towards the vertebral bodies. The side

walls are blocked against invasion of disc material as was described in the literature by Ray. The oval shaped insert requires the drilling of three adjacent holes such that the height is at least twice the width. This concept addressed the same limitations in disc width space versus disc height space as discussed above. The Kuslich et al. implants are not expandable and any potential combination of increased height plus expandability are not disclosed by the Kuslich et al. references.

Furthermore, the Kuslich et al. patents disclose that the semicylindrical arcuate ribs are not tapered for the purpose of prevention of expulsion or pullout after insertion into the prepared disc space, but rather to promote ease of insertion without concern for expulsion except as may be provided by the settling of vertebral spongy bone into the slots between the ribs.

The expandable non-threaded spinal fusion device of the disclosure overcomes the difficulties described above and affords other features and advantages heretofore not available.

### **SUMMARY**

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The device disclosed herein provides a series of resilient supporting arches which act as spacers between the two vertebral bodies, but also permit a simple partial collapse of about 1 mm of soft bone into the spaces between the arches. These arches preferably have parallel slots machined perpendicular to the long access of the implanted device. After insertion of the device, a combination of body weight and muscular contractions applied across the vertebrae and device serve to allow the vertebral bone to descend or sink into the parallel slots of the

device. The vertebral bone will descend or sink across the device to a point that will allow fusion promoting substance, i.e. bone material or any of the well known substitutes such as bone morphologic protein, hydroxyapatite or bone growth factor, placed within the slotted arches to be brought into contact with the bone of the vertebral body. Furthermore, the device can be made in a narrow range of sizes since the two halves of the device are placed into a hole bored between the vertebral bodies and then the halves of the device are forced apart to penetrate into the softer bone of the vertebral spongiosa or cancellous bone. Thus, both the width and height of the devices are separately controlled.

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The cortical portion of the juxtaposed end plate of the vertebra is cut away by a drilling process thereby forming the hole which will accommodate the two halves of the slotted cage. An insertion tool or spreading device delivers the two halves of the cage inside the hole and then spreads the two halves apart to force the parallel ribs of the cage into the recipient soft bone.

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The spreading device elevates and/or separates the two halves of the cage until the outer anulus of the cage becomes abutted tightly against the receiving bone and capable of exerting sufficient counter force to stabilize each of the slotted cages. While being spread apart by the spreading device, notched rod-like spacers of various heights may then be inserted into the lateral stabilizing structures or channels of each cage. Once the notched spacers are inserted, the spreading device is released and removed from within the two halves of the cage. At this time, the recoil force of the outer anulus of the cage will force the lateral portions of each cage against the spacers further stabilizing them.

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In addition, the insertion tool is capable of moving either one of the cage halves further out of or further into the drilled holes of the vertebral body in order to compensate for any slippage between the two vertebral bodies which may have occurred as a result of injury or degeneration. Once the two halves of the cage are situated in the drilled holes of the vertebral body, the insertion tool can then be used to correct the slippage and alignment before the notched spacers are placed. After properly aligning the vertebral bodies, the notched spacers are inserted and positioned along the lateral stabilizer channels of the cage. The insertion or spreading tool is then removed allowing the recoil of the outer anulus of the cage to force the ribs of the slotted arches into the bone, thereby stabilizing the now corrected displacement of the vertebral bodies.

This unique system, therefore, allows for an assortment of diameters of the cages to satisfy a wide variety of heights of the disc spaces. Other objects and advantages of this structure will become apparent from the following detailed description and from the appended drawings in which like numbers have been used to describe like parts throughout the several views.

### BRIEF DESCRIPTION OF THE DRAWINGS

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Preferred embodiments of the present disclosure are described herein with reference to the drawings wherein:

FIG. 1 is a view from the posterior aspect of two adjacent vertebral bodies and the fusion implant device of the disclosure;

FIG. 2A is a view from a lateral aspect illustrating two adjacent misaligned vertebrae;

FIG. 2B is a view from a lateral aspect illustrating two correctly aligned vertebrae using the fusion implant device of the disclosure;

- FIG. 3A is a cross-sectional view of the slotted two fusion implant halves and lateral stabilizers;
- FIG. 3B is a cross-sectional view of various sized notched spacer rods;
  - FIG. 4 is a longitudinal cross-section of the two slotted fusion implant halves and a corresponding spacer rod;
  - FIG. 5 is an exploded isometric view of the slotted fusion implant halves and the insertion-distraction tool;

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- FIG. 6 is a side planar view of the insertion-distraction tool in the closed position;
- FIG. 7 is a side planar view of the insertion-distraction tool in the open position;
- FIG. 8A is a view illustrating an alternative embodiment of the insertion-distraction tool tip;
  - FIG. 8B is a view illustrating an alternative embodiment of the insertion-distraction tool tip; and
- FIG. 9 is a view illustrating the slotted fusion implant halves encasing a core of the bone fusion inducing substance.

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## DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The preferred embodiments of the apparatus and methods disclosed herein are discussed in terms of orthopedic spinal fusion procedures and instrumentation. It is envisioned, however, that the disclosure is applicable to a wide variety of procedures including, but, not limited to ligament repair, joint repair or replacement, non-union fractures, facial reconstruction and spinal stabilization. In addition, it is believed that the present method and instrumentation finds application in both open and minimally invasive procedures including endoscopic and arthroscopic procedures wherein access to the surgical site is achieved through a cannula or small incision.

The following discussion includes a description of the spinal fusion implant utilized in performing a spinal fusion followed by a description of the preferred method for spinal fusion in accordance with the present disclosure.

In the discussion which follows, the term "proximal", as is traditional, will refer to the portion of the structure which is closer to the operator, while the term "distal" will refer to the portion which is further from the operator.

Referring now to the drawings in which like reference numerals identify similar or identical elements throughout the several views, FIGS. 3-5 and 9 illustrate, in perspective, the fusion implant device of the disclosure. Fusion implant device 5 is contemplated to be a self-tapping implant, i.e., the implant is intended to be inserted within a preformed bore in adjacent bone structures, e.g., adjacent vertebrae, without necessitating tapping of an internal thread within the bone structures prior to insertion. Fusion implant device 5 is preferably fabricated from a suitable bio-compatible rigid material such as titanium and/or alloys of

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titanium, stainless steel, ceramic materials or rigid polymeric materials. It is also contemplated that fusion implant device 5, at least partially, be fabricated of bioabsorbable materials.

With reference to FIG. 1, disk vertebrae 1, 2 and an implanted fusion implant device 5 according to the disclosure is shown. A posterior aspect of the two adjacent vertebral disks 1, 2 include a pair of fusion implants 5 containing inserted rod-like spacer inserts 16, 17, 18 and bone fusing material 27 contained therein. The fibers of the ligamentous annulus 3 and the bilateral laminectomies are preformed through the posterior bony structures 4 which surround the fusion implants 5.

As is best depicted in FIGS. 2A and 2B, vertebrae disc 6 is misaligned with respect to vertebrae disc 7 in that disc 6 has slipped forward relative to disc 7. The direction of force necessary to correct the slippage is shown by the opposing arrows near the ligamentous anulus space between the vertebral discs. With the use of the fusion implant device 5 and methods disclosed in the disclosure, it is possible to correct such misaligned discs as is shown in FIG. 2B. Vertebrae discs 8 and 9 are corrected relative to each other with the use of the fusion implant device 5 and are now in proper anatomical alignment.

With reference to FIGS. 3A and 3B, the fusion implant device 5 includes slotted fusion implant halves 10 and their respective lateral stabilizers 12 to which the arches of the fusion implant device 5 are provided in the form of spaced apart slotted ribs 11. The union of the slotted fusion implant halves 10 form a fusion cage 34, as is shown in FIG. 9. As shown in FIG. 3A, the lateral stabilizers 12 include a semi-circular outer periphery, however, the lateral

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stabilizers 12 could also include a less arcuate or horizontal outer periphery thereby allowing the cortical plates to rest upon the lateral stabilizers and further prevent the lateral collapse of the vertebral bodies. Notches 15 line the interior portion of the lateral stabilizer portions 12 along the lateral stabilizer channels 14. The notches 15 of the lateral stabilizers 12 correspondingly engage with notches 20 of the various sized rod spacers 16, 17, 18 when inserted into the lateral stabilizer channels 14. It is to be contemplated that the notches 15 of the lateral stabilizer portions 12 and the notches 20 of the spacers 16, 17, 18 can include like engagement apparatuses such as threads, ribs, teeth or facets. The space 13 between the lateral stabilizer portions 12 is spread apart to accommodate the various heights of spacers 16, 17, 18. In operation, the notches 15 of the lateral stabilizers 12 engage the notches 20 of the spacers 16, 17, 18 and form a single unitary cage 34. The spacers 18 include lateral shoulders 19 which are designed to resist collapse of the fusion implant cage 34 when under a crushing force. After the two implant halves 10 of the fusion implant device 5 have been used to correct the slippage between two vertebrae, the crushing force applied between the notches 15 of the stabilizers 12 and the notches 20 of the spacers 16, 17, 18 will not allow the two vertebra from slipping back into the original misaligned or abnormal position. The spacer inserts 16, 17, 18, as well as the fusion implant halves 10 may also be made of a bioabsorbable material so that they will slowly dissolve as the bone fusion between the two vertebral bodies continues to grow. In doing so, the spacer inserts 16, 17, 18 will slowly transfer the forces resisting collapse back to the resulting bone graft or fusion. Thus, as the bone graft or fusion continues to grow, it will gradually take over the load forces and thereby

enhance the growth and overall strength of the resultant graft or fusion.

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As is best depicted in FIG. 4, the mating relationship between the spacer 16 and the two fusion implant halves 10 is shown. The two fusion implant halves 10 include ribs 11 having sloped surfaces 30 designed to prevent expulsion or pullout of the fusion implant halves 10 under force. The sloped surfaces 30 of the ribs 11 may vary in degree to a slope which is dependent upon the amount of force expected to act upon the inserted fusion device 5. Once chosen for appropriate height, spacer 16 showing notches 20 is inserted into the space 13 between the lateral stabilizer portions 12. Spacer 16 including notches 20 will then be matingly fitted with the notches 15 of the lateral stabilizer portions 12.

With reference to FIGS. 5-7, insertion-distraction tool 21 is designed to accommodate the various potential lengths of fusion implant halves 10. Insertion-distraction tool 21 includes limit stops 22 which prevents tool 21 from being over inserted into the fusion implant halves 10. The tool 21 includes lateral retaining ribs 23 which are designed to grab the internal portions of slotted ribs 11 of fusion implant halves 10. The lateral retaining ribs 23 allow for the insertion-distraction tool 21 to be displaced relative to each other in order to permit realignment of slippage of one vertebra disc relative to another vertebrae disc.

The insertion-distraction tool 21, as shown in FIG. 6, includes handles 25 which are normally displaced apart from one another when the insertion-distraction tool 21 is in a resting or spread apart position. In this resting position, the tool tips 24 are positioned closed so that the tool 21 may be inserted within the fusion device halves 10. In operation, tool tips 24 are inserted within the fusion device halves 10 until limit stops 22 abut against a proximal slotted rib

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11. The central hinge point 26 of tool 21 defines the motion of the handles 25 moving extension mass 29 of the tips 24 around hinge points 27 which causes spreading apart or closing of the tips 24. Two cross members 28 articulate with extension masses 20 to maintain tips 24 parallel with respect to one another when being spread apart by the actuation of handles 25.

The insertion-distraction tool 21, as shown in FIG. 7, includes handles 25 which are in a closed position and tips 24 which are spread apart in a parallel relationship. In this position, the tips 24 are used to spread the fusion implant halves 10 in a manner parallel to the cortical end plates of the vertebral bodies. A means to shift the location (not shown) of the hinge point 26 would allow the tips 24 to open in a slightly non-parallel fashion as may be needed for the final positioning of the fusion implant halves 10. A ratchet locking means (not shown) to hold the handles 25 in the desired position can be provided to maintain the spreading of the vertebral disc space as the fusion implant halves 10 are positioned.

With reference to FIGS. 8A and 8B, alternate embodiments of the insertion-distraction tool 21 are shown. A single pair of broad tips 31 can be used to spread the central core of the fusion implant halves 10 into the vertebral bone. In an alternative embodiment, a dual pair of narrower tips or blades 32 can be used within the lateral stabilizer channels 14 to spread the fusion implant halves 10. The blades 32 include a central bow 33 which are designed to permit the passage of a central core preform of fusion inducing substance 27.

A pair of slotted fusion implant halves 10 including supporting ribs 11 and lateral stabilizer shoulders 12 are shown in FIG. 9. The insertion-

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distraction tool 21 with paired tips 24 or 31 or 32, as discussed above, engages the notches 15 of the lateral stabilizers 12 on both sides of the fusion implant halves 10 spreading them apart to permit the insertion of a preformed porous solid core of fusion inducing substance 27. The porous core 27 may be preformed so that semicircular ridges on the external periphery of the porous core 27 project into and out of corresponding slots 28 between the ribs 11 of the fusion implant halves 10. The porous core 27 is of sufficient strength to withstand the compressive forces between the vertebral bodies as the fusion of the bones develops. Porous cores 27 of various sizes are used to accommodate various disc heights. A temporary spacer porous core (acting simply as a spacer) may be initially placed on one side of the vertebral bodies for partial spreading of the disc space. The second vertebral side will then receive a full height porous core 27. Finally, returning to the first side of the vertebral bodies, the temporary spacer porous core is removed and a permanent porous core 27 is placed within the disc space between the fusion implant halves 10. For further stabilization, if needed, appropriately shaped rods, screws or other similar spacing-type apparatuses may be driven into the lateral stabilizer channels 14 and driven along the length of the stabilizers 12 to add the needed stabilization throughout the implant procedure.

A preferred embodiment of the present fusion implant system includes a slotted fusion implant device 5 to be implanted in and promote fusion with respect to one or more bone structures wherein the fusion implant system contains a bone fusion inducing substance 27, such as bone material, bone morphologic protein, hydroxyapatite or bone growth factor, packed therein.

Preferably, the fusion implant system includes a fusion implant having two halves

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10 consisting of slotted arches or ribs 11 having an outside radius and an inside radius with deep complete perforations between the arches 11 where the outer portion and inner portion of the arches 11 become confluent. The fusion implant system also includes lateral notched spacer rods 16, 17, 18 having a semi-circular outer periphery that attach along the longitudinal axis of the lateral stabilizers 12 providing a base for them. Also, dependent on the shape of the corresponding lateral stabilizers 12, the spacer rods 16, 17, 18 could include a less arcuate or horizontal outer periphery. The lateral stabilizers 12 have threads or notches 15 along their internal diameters extending along the length of the fusion implant 5. As shown in Figure 4, the circular ribs 11 have slopes of 30 degrees to 45 degrees relative to the longitudinal axis of the fusion implant 5 providing additional resistance to axial displacement or expulsion of the fusion implant halves 10.

Upon placement of both fusion implant halves 10 opposite to each other within a bore drilled between two vertebral bodies, the fusion implant halves 10 may be forced apart so that the circular ribs 11 are forced into the softer cancellous bone of the vertebral bodies, thus stabilizing the fusion implant halves 10 within each opposing vertebral body. Lateral stabilizers 12 containing threads or notches 15 are used to accommodate notched rod spacers 16, 17, 18 of various heights that are placed after the fusion implant halves 10 are forced apart in order to maintain the new distracted height of the vertebral bodies after the fusion implant halves 10 have been implanted.

The internal cavity of the two fusion implant halves 10 will accommodate a fusion growth inducing substance 27 either as a preformed core or as separate morsels and protect that substance from extrusion or collapse by the

semi-circular ribs 11 of the fusion implant halves 10. Once the fusion implant halves 10 have been fully distracted and the semi-circular ribs 11 have penetrated into the vertebral bodies, notched spacer rods 16, 17, 18 are placed laterally along the lateral stabilizers 12 wherein the notches 20 of spacers 16, 17, 18 engage the notches 15 of the lateral stabilizers 12, thus holding the fusion implant halves 10 firmly apart and preventing axial displacement of the two halves 10 relative to each other's position.

The fusion implant system is installed with an insertion-distraction tool 21 capable of separating the two fusion implant halves 10 to the appropriate distraction which allow for the placement of spacers 16, 17, 18 before removal of the tool. The tool 21 preferably has two halves, as shown in Figure 5, with each half having notches or prominences 23 around their diameter that engage the internal rib structure 11 of the fusion implant halves 10 to prevent their displacement relative to the tool 21. The two halves of the insertion-distraction tool 21 may be axially displaced relative to each other in order to move the position of the fusion implant halves 10 and thereby the now attached vertebral bodies for the purpose of realignment of a displacement of the two vertebral bodies relative to each other. The tool 21 includes jack-like scissor linkage, as described earlier, to keep the jaw-like tool halves and tips 24 generally parallel.

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The fusion implant system of the present disclosure, therefore, has the novel ability to adapt to varying vertebral bodies as to the softness of their bone, width of the disc space and then to allow sufficient corrective force to permit realignment of the pathologically displaced vertebra.

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In operation, the novel fusion implant system can be implanted by the following method using a standard surgical approach as though a laminectomy or discectomy is to be performed on either side of the vertebral body. Prior to the act of drilling bore holes into the vertebral bodies, the nerve structures are displaced first to one side and then to the other side in order to avoid contact with the intervertebral drill. Two bore holes are drilled to the appropriate depth, extending at least 75% of the total intradiscal front to back diameter. The bore holes should penetrate through the end plates bilaterally and be between 1 to 3 mm in depth into the cancellous portion of the vertebral bodies. The bore holes would normally be between 10-14 mm in diameter. The two arched halves 10 of the fusion implant device 5 are then mounted on the insertion-distraction tool 21 and inserted into one of the drilled holes. One drill hole is fitted with the fusion implant device 5 and then the other drill hole is similarly fitted. The insertiondistraction tool 21 seats the fusion implant device 5 deeply within the hole to a point where the tool 21 abuts against the posterior margin of the hole, as determined by the limit stops 22 which are machined on the tool 21. Distraction of the tool 21 then forces the sloped surfaces or sharpened edges 30 of the ribs 11 of the implant halves 10 deeply into the cancellous bone. Further, the distraction tool 21 spreads the space until the anulus of the fusion implant device 5 is quite firmly seated and within normal intervertebral distance. Appropriate elongated spacers 16, 17, 18 are then inserted into the space 13 between the lateral stabilizers 12 engaging small notches 15 within the lateral channels 14 to prevent slippage of one fusion implant half 10 relative to the other along the common axis of penetration. The height of the spacers 16, 17, 18 is chosen to provide

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sufficient firmness to the anulus where a counter force will then hold the fusion implant halves 10 and its lateral spacers 16, 17, 18 in firm axial alignment relative to each other. The tool 21 is then released and removed allowing the full outer anulus force to be exerted against the fusion implant halves 10 and the spacers 16, 17, 18. The cage 34 is then packed with an appropriate amount of bone fusion inducing substance 27 such as an autograft or allograft. A ceramic insert may be fitted for the cage 34 or small portions of hydroxylapatite may be packed inside the cage 34. This packing of the fusion inducing material 27 further provides strength so as to resist the potential collapse of the cage 34 or the over penetration of the slotted ribs 11 into the recipient bone bed.

An additional method for the surgical procedure would best be used on patient's having a degenerative or traumatic slippage of one vertebra upon the other. In this case, the procedure would be different, in that, after the elevation or spreading of the implant halves 10, one portion of the insertion tool 21 would then slide inward or outward relative to the other implant half 10 and insertion tool 21 so that the bone into which the implant half 10 has been inserted may be realigned relative to each other along their anterior-posterior axes. Once repositioned, the system should be sufficiently stable to resist re-slippage or misalignment after the tool 21 has been removed. This procedure may require that one implant half 10 be inserted deeper relative to the other before the realignment process begins. After spreading the space and forcing the implant halves 10 into the recipient bone beds the halves 10 and the attached vertebral bodies would be appropriately repositioned. This corrected position would be secured by effectively locking the notched portions 15 of the lateral stabilizers 12 into the

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notched portions 20 of spacer rods 16, 17, 18. The notches 20 the spacer rods 16, 17, 18 would be forced tightly into the corresponding notches 15 of the lateral stabilizers 12 by the forces of the anulus recoil and body weight of the patient. These forces would prevent the now corrected vertebral alignment from any further slippage.

A further method uses a spreader means to elevate the two sides of a semicircular fusion insert half 10 by its transverse slots 28 such that a suitable fusion core insert 27 may be installed inside the central core of the fusion implant cage 34. This method provides that the lateral slots 28 be elevated while a central core insert 27 of correct height is placed within the fusion implant halves 10. This core insert 27 should be made of a porous bone growth inducing substance to create a fusion between the core substance and the vertebral body bone beds which are apparent across the slots 28. This method may use a preformed core 27 of sufficient strength to support the vertebral load during fusion development. This current method is in contrast with the previously discussed method which requires the packing of morsels of fusion inducing substance 27 after the fusion implant device 5 is placed within the vertebral bodies. Lateral transverse notched spacer rods 16, 17, 18 may additionally be placed if further stability is needed. The preformed insert 27 may have mating grooves to fit within the slots 28 of the fusion implant 5 to partially fill the slots 28 and provide additional anteriorposterior resistance to slippage (spondylolisthesis). When a preformed core 27 is used having semicircular elevations to match the fusion insert slots 28; the implant halves 10 may be independently repositioned using the appropriate insertiondistraction tool 21 to correct any slippage. The mated elevations and grooves of

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the preformed core 27 then serve as a means to prevent a return to the slipped or misaligned position.

In operation, the alternative embodiments and methods of the fusion implant system can be implanted by the following method using a standard surgical approach as though a laminectomy or discectomy is to be performed on either side of the vertebral body. Prior to the act of drilling bore holes into the vertebral bodies, the nerve structures are displaced first to one side and then to the other side in order to avoid contact with the intervertebral drill. Two bore holes are drilled to the appropriate depth, extending at least 75% of the total intradiscal front to back diameter. The bore holes should penetrate through the end plates bilaterally and be between 1 to 3 mm in depth into the cancellous portion of the vertebral bodies. The bore holes would normally be between 10-14 mm in diameter. The lateral slots 28 of the two arched halves 10 of the fusion implant device 5 are then mounted on the insertion-distraction tool 21 and inserted into one of the drilled holes. One drill hole is fitted with the fusion implant device 5 and then the other drill hole is similarly fitted. The insertion-distraction tool 21 seats the fusion implant device 5 deeply within the hole to a point where the tool 21 abuts against the posterior margin of the hole, as determined by the limit stops 22 which are machined on the tool 21. Distraction of the tool 21 then forces the sloped surfaces or sharpened edges 30 of the ribs 11 of the implant halves 10 deeply into the cancellous bone. Further, the distraction tool 21 spreads the space until the anulus of the fusion implant device 5 is quite firmly seated and within normal intervertebral distance. A preformed core 27 of appropriate size is then inserted into the central cavity of the fusion implant device 5. This core exerts

force against the ribs 11 of the slotted fusion insert halves 10 which in turn force the ribs 11 into the vertebral bone bed. The correct height of the core provides sufficient firmness to the anulus where a counter force will then hold the fusion implant halves 10 in firm axial alignment relative to each other. The tool 21 is then released and removed allowing the full outer anulus force to be exerted against the fusion implant halves 10 and the preformed core 27.

When the relationship between the two adjacent vertebral bodies is considerably altered, any of the procedures above may be performed incrementally. That is, part of the needed correction or realignment may be performed temporarily on one side with the placement of an intermediate sized spreading or correcting insert. That first side with its intermediate correction is then temporarily abandoned while a fully correcting insert is permanently placed on the second side. Then, returning again to the first side, the temporary partial correcting insert is removed and replaced with a permanent insert equal to the one on the second side, thereby fully correcting or realigning the two vertebrae. Effectively, this method permits a more gradual change in the misalignment which at times may be necessary as the collagen fibers of the ligamentous anulus of the disc sometimes stretch slowly and an initial attempt at full correction on only the first side may cause tearing of these fibers or fracture of the vertebral bone.

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It will be understood that various modifications may be made to the embodiments disclosed herein. For example, the fusion implant device may incorporate more than two fusion implant sections within a single bore or the external ribs may include a pointed edge with a slope greater than 45 degrees.

Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

### WHAT IS CLAIMED IS:

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1. A fusion implant system for promoting fusion of adjacent bone structures wherein the fusion implant system contains a bone fusion inducing substance packed therein, the fusion implant system comprising a fusion implant having at least two sections, each section including arches and at least two lateral stabilizers having a longitudinal axis transverse to the arches.

- 2. The fusion implant system according to claim 1, wherein the lateral stabilizers include channels along the longitudinal axis and the arches include slots.
- 3. The fusion implant system according to any one of claims 1 or 2, further including at least one spacer to be matingly received within the channels of each lateral stabilizer.
  - 4. The fusion implant system according to claim 3, wherein the at least one spacer includes a set of various sized spacers for varying a distance between the at least two sections.
- The fusion implant system according to any one of claims 3 or 4, wherein the at least one spacer further includes engagement apparatus along its transverse outer periphery.

 The fusion implant system according to claim 5, wherein the channels further include engagement apparatus along their transverse inner periphery.

- 7. The fusion implant system according to claim 6, wherein the
   5 engagement apparatus of both the channels and the spacers engage each other
   when the fusion implant system is implemented.
  - 8. The fusion implant system according to any one of claims 1-7, wherein the system is made at least partially from a bio-absorbable material.
- 9. The fusion implant system according to any one of claims 1-8,
  wherein the fusion implant is placed within a hole drilled between the two adjacent
  bone structures and wherein the fusion implant is pressed against surrounding
  walls of the hole so that the arches are pressed into the surrounding walls of the
  hole.
- 10. The fusion implant system according to claim 9, wherein the at least one spacer is interposed within the channels of the lateral stabilizers, wherein the spacers are chosen to correspond to a particular height between the fusion implant pressed against the walls of the hole.

11. A method for fusion of adjacent vertebrae having a disk space therebetween, the method comprising the steps of:

accessing the disk space and forming a bore therein;

implanting a fusion implant device within the bore, the fusion implant device including at least two sections, each section including arches and at least two lateral stabilizers having a longitudinal axis transverse to the arches, each lateral stabilizer having a channel along the longitudinal axis;

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positioning the at least two sections of the fusion implant within the bore so that the arches penetrate the bone material of the adjacent vertebrae and defining a core area therebetween; and

inserting a spacer along the channel of each lateral stabilizer.

12. The method according to claim 11 wherein the step of positioning includes:

inserting an insertion tool within the bore, the insertion tool including a handle and a tip structure, the tip structure being received within the bore; and

expanding the tip structure within the bore against the at least two sections of the fusion implant thereby forcing the arches into adjacent bone material.

13. The method according to any one of claims 11 or 12, further comprising the step of packing the core area with fusion promoting material.

14. The method according to any one of claims 11-13, wherein the channels of the lateral stabilizers and the spacers include mating apparatus to thereby enhance engagement of the lateral stabilizers and the spacers during the inserting step.

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- 15. The method according to any one of claims 11-14, wherein the spacer further includes a set of various sized spacers for varying a distance between the at least two sections.
- 16. A nonthreaded fusion implant system to be implanted in and promote fusion within one or more bone structures, wherein the fusion implant system contains a bone fusion inducing substance packed therein, the fusion implant system comprising:

a fusion implant comprising two halves, each half including arches having an outside portion and an inside portion, wherein the outside portion and the inside portion meet at a confluent edge;

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lateral stabilizers positioned along a longitudinal axis of each fusion implant half, the lateral stabilizers having notches or threads along an internal periphery along the longitudinal axis;

slotted spacers positioned along the longitudinal axis of the lateral stabilizers; and wherein the confluent edges of the arches include a slope between 30 and 45 degrees relative to the longitudinal axis of the fusion implant halves.

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17. The nonthreaded fusion implant system according to claim 16, wherein the halves of the fusion implant are positioned within a bore within the bone structures and wherein the halves are forced apart so that the arches are pressed into soft surrounding bone of the bone structures.

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18. The nonthreaded fusion implant system according to claim 17, further comprising notches or threads along a portion of the outer periphery of the slotted spacers, and wherein the slotted spacers are positioned within the lateral stabilizers to maintain a desired distracted and axial position between the fusion implant halves.

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19. The nonthreaded fusion implant system according to claim 18, further comprising a protective cavity formed between the fusion implant halves once in the distracted and axial positions, wherein the bone fusion growth inducing substance is placed within the protective cavity.

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20. The nonthreaded fusion implant system according to claim 18, further comprising an insertion tool having a tip section which is capable of the forcing apart of the fusion implant halves so that the slotted spacers may be positioned within the lateral stabilizers.

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21. The nonthreaded fusion implant system according to claim 20, wherein the tip of the insertion tool further includes notches to engage the fusion implant halves between the arches to thereby prevent the fusion implant halves from being displaced with respect to the insertion tool during the positioning of the fusion implant halves within the bore.

- 22. The nonthreaded fusion implant system according to claim 20, wherein the tip section of the insertion tool further includes dual tips separated along a longitudinal axis of the insertion tool, wherein each tip can be axially displaced relative to each other along the longitudinal axis of the insertion tool.
- The nonthreaded fusion implant system according to claim 20, wherein the tip section of the insertion tool further includes separate blade sections to be inserted along the longitudinal axis of each lateral stabilizer, the separate blade sections forming a bow section therebetween capable of allowing the bone fusion growth inducing substance to be inserted through the bow section.
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  24. The nonthreaded fusion implant system according to claim 16,
  wherein the bone fusion growth inducing substance is a force bearing porous
  preformed core insert.

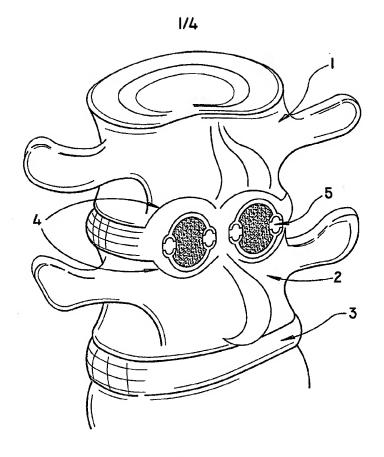


FIG. I

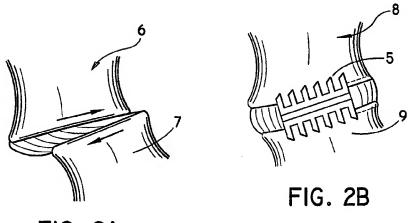
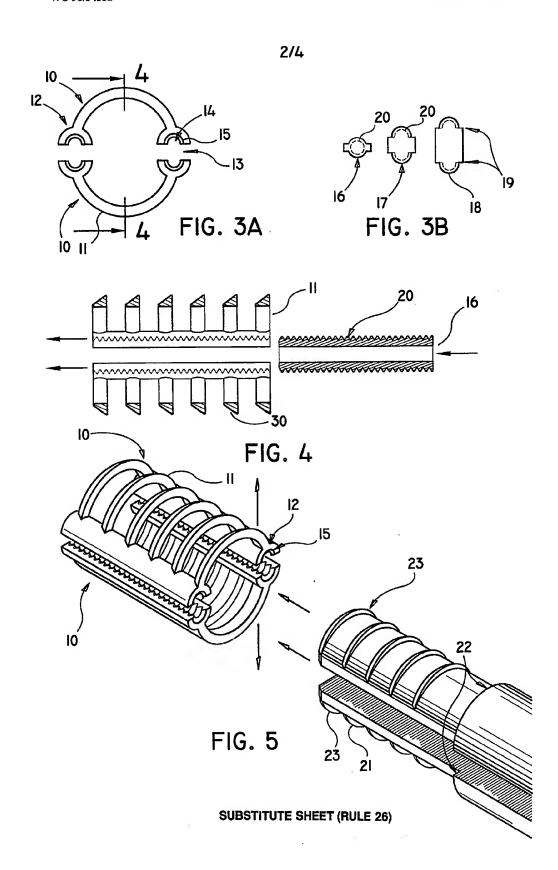
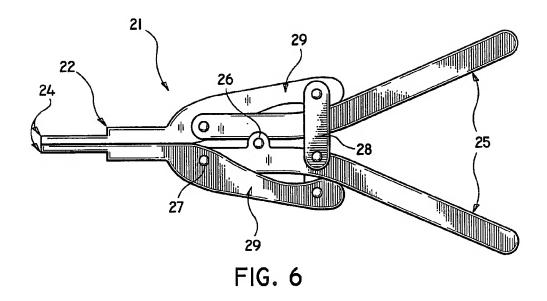


FIG. 2A

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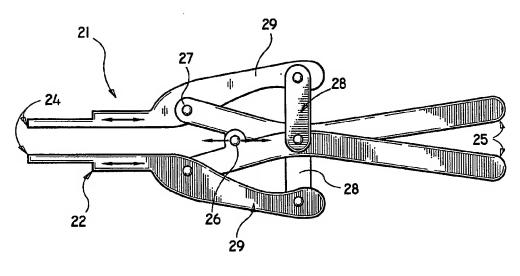
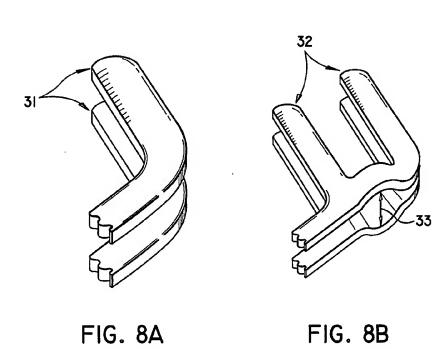


FIG. 7

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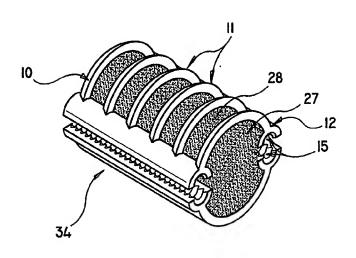


FIG. 9

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# INTERNATIONAL SEARCH REPORT

International application No. PCT/US98/02148

A. CLASSIFICATION OF SUBJECT MATTER			
IPC(6) :A61B 17/70			
US CL :606/61 According to International Patent Classification (IPC) or to both national classification and IPC			
B. FIELDS SEARCHED			
Minimum documentation searched (classification system followed by classification symbols)			
U.S. : 606/61, 60, 72, 73; 623/17			
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched			
none		· .	
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)			
none			
110110			
	TO BE DELEVANT		
C. DOCUMENTS CONSIDERED TO BE RELEVANT			
Category*	Citation of document, with indication, where appr	ropriate, of the relevant passages	Relevant to claim No.
	US 5,609,636 A (KOHRS ET AL.)	MARCH 1997, SEE ENTIRE	1
X, P	REFERENCE.		
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Further documents are listed in the continuation of Box C. See patent family annex.			
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## INTERNATIONAL SEARCH REPORT

International application No.
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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)	╛
This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:	
1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:	
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3. X Claims Nos.: 5, 8-10, 14,15 because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).	
Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)	
This International Searching Authority found multiple inventions in this international application, as follows:	
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2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payra of any additional fee.	nt
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No required additional search fees were timely paid by the applicant. Consequently, this international search report restricted to the invention first mentioned in the claims; it is covered by claims Nos.:	t is
Remark on Protest  The additional search fees were accompanied by the applicant's protest.	
No protest accompanied the payment of additional search fees.	



## **PCT**

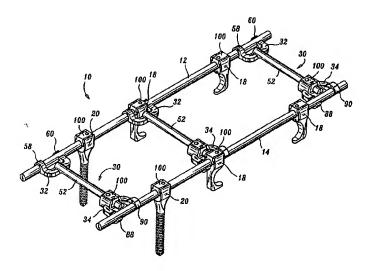
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(30) Priority Data:		US		port. te time limit for amending the ed in the event of the receipt of
(72) Inventor: NICHOLS, David; 40 Salem Road, Trum 06611 (US).	nbull, (	CT		
(74) Agent: GERSHON, Neil, D.; United States Surgical tion, 150 Glover Avenue, Norwalk, CT 06856 (US		ra-		

#### (54) Title: APPARATUS FOR SPINAL STABILIZATION



#### (57) Abstract

An apparatus is disclosed for connecting first, and second elongated spaced apart spinal rods to one another which includes a first connector (32) having structure to engage a first spinal rod (12) at a location along the length thereof and an elongated beam (52), having an axis extending in a direction transverse to the first spinal rod, a second connector (34) having structure to engage a second spinal rod (14) at a location adjacent the first connector, including a reception portion (72) projecting in a direction transverse to the second spinal rod, and defining a channel (82) for receiving the elongated beam of the first connector, a locking member (100) dimensioned, configured to engage the channel along the axis of the beam, and secure the position of the beam with respect thereto.

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#### **APPARATUS FOR SPINAL STABILIZATION**

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#### **BACKGROUND OF THE INVENTION**

#### 1. Field of the Invention

The subject disclosure relates to implantable spinal stabilization systems for surgical treatment of spinal disorders, and more particularly, to an apparatus for connecting cylindrical spinal rods of a spinal stabilization system to one another across the spinous process.

#### 2. Background of the Related Art

The spinal column is a complex system of bones and connective tissue which protects critical elements of the nervous system. Despite these complexities, the spine is a highly flexible structure, capable of a high degree of curvature and twist through a wide range of motion. Trauma or developmental irregularities can result in spinal pathologies which limit this range of motion.

For many years, orthopedic surgeons have attempted to correct spinal irregularities and restore stability to traumatized areas of the spine through immobilization. Over the past ten years, spinal implant systems have been developed to achieve immobilization. Examples of such systems are disclosed in U.S. Patent Nos. 5,102,412 and 5,181,917. Such systems often include spinal instrumentation having connective structures such as elongated rods which are placed on opposite sides of the portion of the spinal column intended to be immobilized. Screws and hooks are commonly utilized to facilitate segmental attachment of such connective structures to the posterior surfaces of the spinal laminae, through the pedicles, and into the vertebral bodies. These components provide the necessary stability both in tension and compression to achieve immobilization.

It has been found that when a pair of spinal rods are fastened in parallel on either side of the spinous process, the assembly can be significantly strengthened by using at least one additional rod to horizontally bridge the pair of spinal rods. An example of a cross brace assembly of this type is disclosed in U.S. Patent No. 5,084,049. Devices such as these commonly consist of a threaded rod for providing the desired lateral support. The threaded rod is fastened to each of the spinal rods by clamps located on each end thereof. However, this configuration is bulky and can cause irritation of the patient's back muscles and other tissue which might rub against the device. A cross brace assembly that fits closer to the spine, preferably in the same general plane as the cylindrical spinal rods, would reduce the complications associated with bulkier devices.

Most existing transverse connectors consist of rods, plates, and bars linked to the longitudinal rods by coupling mechanisms with set screws, nuts, or a combination of each. These connectors require several components and instruments to build the constructs. Each additional component or instrument required to assemble the connectors adds to the complexity of the surgical procedure. Examples of connectors constructed from multiple components are disclosed in U.S. Patent Nos. 5,312,405, 5,334,203 and 5,498,263.

It would be beneficial to provide an improved device to transversely connect spinal rods of a spinal stabilization system to one another which utilizes a minimum number of components parts and which reduces the posterior horizontal profile and overall bulkiness of the system.

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#### SUMMARY OF THE DISCLOSURE

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The subject disclosure is directed to an apparatus for connecting two spinal rods of a spinal stabilization system to one another in such a manner so as to provide an adjustable low-profile rigid linkage there between. The apparatus disclosed herein includes a first connector having a pair of opposed spaced apart arcuate engaging members associated therewith for engaging a first elongated spinal rod at a location along the length thereof. The first connector further includes an elongated connective beam which extends in a direction transverse to the first spinal rod to form a bridge across the spinous process.

The apparatus further includes a second connector having a pair of opposed spaced apart arcuate engaging members associated therewith for engaging a second spinal rod at a location adjacent the first connector. The second connector includes a reception portion which projects in a direction transverse to the second spinal rod and defines a channel for receiving the elongated beam of the first connector. The apparatus further includes a locking member which is dimensioned and configured to linearly engage the channel and positively secure the position of the elongated beam with respect thereto.

The channel of the reception portion is preferably defined by a base portion having a planar surface and a pair of opposed spaced apart upstanding side walls. The elongated beam preferably has a semi-circular transverse cross-section, with a lower surface thereof being planar and an upper surface thereof being arcuate. In this embodiment, when the apparatus is installed, the planar lower surface of the elongated beam is disposed in face-to-face contact with the planar surface of the base portion of the reception channel. The locking member preferably includes a lower body portion having a lower surface with an hemi-cylindrical channel for accommodating the upper arcuate surface of the elongated beam.

In addition, the locking member preferably includes a mechanism designed to provide secure fixation of the elongated connective beam of the first connector within the reception channel of the second connector. The mechanism is defined in part by a pair of laterally opposed tapered wedges configured to engage complementary tapered slots defined in the opposed spaced apart upstanding side walls of the reception channel.

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The mechanism is preferably further defined by a pair of reception ports located on each of the lateral sides of the upper body portion of the locking member. The reception ports are spaced above the tapered wedges and are positioned at locations adjacent the opposed leading and trailing ends of the upper body portion of the locking member. The locking tabs are configured to positively receive and engage corresponding complementary locking tabs projecting from the interior surfaces of the opposed spaced apart upstanding side walls of the reception channel.

Because the tapered wedges of the locking member engage the slots of the reception channel linearly along the axis of the elongated connective beam, the application of undesirable torsional forces to the spine normally generated during the process of tightening a conventional threaded component is avoided. Moreover, while threaded components can loosen under cyclically applied loads commonly encountered by the spinal column, the secure locking mechanism of the locking member remains fixed under such conditions.

The subject disclosure is also directed to a connecting member for connecting a transverse spinal rod to a longitudinal spinal rod comprising a base portion, a pair of spaced apart arcuate engaging members extending in a first direction from the base portion to engage the longitudinal spinal rod, and a pair of upstanding walls extending in a direction transverse to the first direction and forming a channel therebetween to receive the transverse spinal rod.

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The subject disclosure is also directed to a connecting member for connecting a transverse spinal rod to a longitudinal spinal rod comprising a base portion, a pair of upstanding walls extending from the base portion forming a channel to receive a transverse spinal rod in a first plane, and a pair of arcuate engaging members extending from the base portion to engage the longitudinal rod in substantially the same plane as the first plane.

A system for spinal stabilization is also disclosed comprising first and second elongated spinal rods, at least one fastening device for securing the first and second spinal rods to first and second sides of the spine, first and second connectors for engaging the spinal rods, and a locking member to secure a connective beam of the first connector to the second connector as described herein.

These and other features of the apparatus disclosed herein and the method of installing the same will become more readily apparent from the following description of the drawings.

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#### **BRIEF DESCRIPTION OF THE DRAWINGS**

So that those having ordinary skill in the art to which the disclosed apparatus appertains will more readily understand how to construct and use the same, reference may be had to the drawings wherein:

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Fig. 1 is a perspective view of a spinal stabilization system for immobilizing a region of the spinal column which includes rod connecting apparatus constructed in accordance with a preferred embodiment of the subject disclosure;

Fig. 2 is a top plan view of the spinal stabilization system of Fig. 1 implanted on the posterior side of the spinal column;

Fig. 3 is a side elevational view of the spinal stabilization system of Fig. 1 implanted on the posterior side of the spinal column;

Fig. 4 is a perspective view of a first connector which forms part of the rod connecting apparatus illustrated in Fig. 1;

Fig. 4A is a perspective view of the first connector showing its rotation to clamp onto the longitudinal rod of the spinal stabilization system;

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Fig. 5 is a perspective view of a second connector which forms part of the rod connecting apparatus illustrated in Fig. 1, together with the locking member operatively associated therewith;

Figs. 6 through 9 illustrate the sequential operative steps for connectively securing the first and second connector components of the rod connecting device illustrated in Fig. 1 (the longitudinal rods have been omitted for clarity);

Fig. 10 is a perspective view of a bone screw constructed in accordance with a preferred embodiment of the subject disclosure which is employed with the spinal stabilization system illustrated in Fig. 1, and which includes a locking member as used in conjunction with the connector of Fig. 5; and

Fig. 11 is a cross-sectional view taken along line 11-11 of Fig. 5 illustrating the locking features of the second rod connector component;

Fig. 12 is a cross-sectional view taken along line 12-12 of Fig. 10 illustrating the locking features of the bone screw; and

Fig. 13 is a perspective view of an alternate embodiment of a connecting apparatus connecting two longitudinal rods.

These and other features of the apparatus disclosed herein will become more readily apparent to those having ordinary skill in the art from the following detailed description taken in conjunction with the drawings.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

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Referring now to the drawings wherein like reference numerals identify similar structural elements of the subject apparatus, there is illustrated in Fig. 1 a spinal stabilization system constructed in accordance with a preferred embodiment of the subject disclosure and designated generally by reference numeral 10.

Referring to Fig 1. in conjunction with Figs. 2 and 3, stabilization system 10 includes a pair of elongated (longitudinal) spinal rods 12 and 14 deployed in parallel on either side of the spinous process 16. Spinal rods 12 and 14 are of a conventional type, constructed from a biocompatible material and having a circular cross-section with a smooth outer surface finish. Spinal rods 12 and 14 are segementally secured to the bones of the spine by a variety of different structural components including, for example, spinal hooks 18 and bone screws 20. The construction of bone screw 20 and hook 18 will be described in greater detail hereinbelow with specific reference to Figs. 11 and 12.

It has been found that when a pair of spinal rods are fastened to one another in parallel on either side of the spine, as illustrated for example in Figs 2 and 3, the stabilization system can be significantly strengthened. Thus, the spinal rods 12 and 14 of stabilization system 10 are connected to one another by readily adjustable, low-profile rod linking devices constructed in accordance with a preferred embodiment of the subject disclosure and designated generally by reference numeral 30.

With continuing reference to Figs. 1 through 3, each rod coupling device 30 includes first and second rod connectors 32 and 34 which are independently engaged to spinal rods 12 and 14, respectively, by a rod engagement mechanism which will be described in detail hereinbelow with reference to Figs. 4 and 5. In accordance with the subject disclosure, the first and second rod connectors 32 and 34 are transversely coupled

to one another by a securement mechanism which will also be described in detail hereinbelow.

Referring now to Figs. 4 and 5, there are illustrated each of the components which define the rod coupling device 30 of the subject invention. With specific reference to Fig. 4, the first rod connector 32 includes a yoke 44 defined by a base portion 46 and a pair of spaced apart arms 48 and 50 which depend from the base portion and define a gap 49 therebetween. An elongated connective beam 52 depends from base portion 46 in a direction opposite the pair of spaced apart arms 48 and 50 to traverse the spinous process. Connective beam 52 preferably has a semi cross-sectional configuration defined by an arcuate upper surface 52a and a planar lower surface 52b. Oppositely facing mirror-image rod engaging structures 58 and 60 having the form of arcuately shaped clips (see also Fig. 11) depend from the ends of arms 48 and 50, respectively, for securely clamping the first connector 32 to spinal rod 12 during a spinal stabilization procedure.

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The arcuate rod engaging structures or clips 58 and 60 each have an inner diameter that is slightly less than the outer diameter of spinal rod 12. During installation of connector device 30, rod connector 32 is first positioned so that longitudinal rod 12 lies in gap 49 and clips 58 and 60 are on opposite sides of the rod 12. Then, connector 32 is rotated relative to spinal rod 12 (see Fig. 4A), causing deflection of the depending arms 48 and 50 and diametrical expansion or spreading of the arcuate rod engaging clips 58 and 60 which facilitates clamping of connector 32 onto spinal rod 12.

Referring to Fig. 5, there is illustrated the second connector 34 of rod linking device 30 which includes a yoke 64 defined by a base portion 66 and a pair of spaced apart arms 68 and 70 which depend from the base portion and define a gap 70 therebetween. A reception portion 72 projects from the base portion 66 of yoke 64 in a direction orthogonal to the direction of the pair of spaced apart arms 68 and 70 to receive

the free end of connective beam 52 when it traverses the spine. Reception portion 72 is defined by a base 76 and a pair of opposed spaced apart upstanding walls 78 and 80 which extend transverse to both the base portion 66 and arms 68 and 70 and which delineate a linear channel 82 therebetween. Oppositely facing mirror-imaged rod engaging structures 88 and 90 having the form of arcuately shaped clips depend from the ends of arms 68 and 70, respectively, for securely clamping the second connector 34 to spinal rod 14 during a surgical procedure.

As described hereinabove with respect to connector 32, the arcuate rod engaging structures or clips 88 and 90 of second connector 34 each have an inner diameter that is slightly less than the outer diameter of spinal rod 14. During installation, rotation of connector 34 relative to spinal rod 14 causes the deflection of depending arms 68 and 70 and the diametrical expansion or spreading of the arcuate rod engaging clips 88 and 90 which facilitates clamping of connector 34 onto spinal rod 14.

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With continuing reference to Fig. 5, rod linking device 30 further includes a locking member 100 having a lower portion 112 and an upper portion 114. The lower portion 112 includes a pair of laterally opposed tapered wedges 116 and 118 defined by a construct which employs an inwardly angled sloping locking surface. The tapered wedges 116 and 118 are dimensioned and configured to linearly engage correspondingly configured slots 126 and 128 defined in upstanding walls 78 and 80. (see Fig. 11). The lower portion 112 of locking member 100 further includes a hemi-cylindrical channel 120 extending along the longitudinal axis thereof for accommodating the arcuate upper surface of 52a of connective beam 52 when it traverses the spinous process and is received by the reception portion 72 of the second connector 34. At such a time, the planar lower surface 52b of connective beam 52 is in face-to-face contact with the planar surface of the base 76 of reception portion 72.

With continuing reference to Fig. 5 in conjunction with Fig. 11, the upper portion 114 of locking member 100 further includes a provisional securement (locking) mechanism consisting of laterally opposed paired retention ports 132, 134 and 136, 138. Laterally opposed retention ports 132 and 136 are disposed adjacent the leading end of locking member 100 while laterally opposed retention ports 134 and 138 are disposed adjacent the trailing end of locking member 100. The paired retention ports are dimensioned and configured to receive and securely retain corresponding paired engagement tabs 142, 144 and 146, 148 which project into the linear channel 82 from the opposed upstanding side walls 78 and 80 of reception portion 72. This provisional locking maintains the locking member 18 in place until it is fully locked upon full engagement of tapered wedges 116, 118 and slots 126, 128.

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Turning now to the hooks and screws for connecting spinal rods 12 and 14 to the vertebrae, and referring first to Fig. 10, there is illustrated a bone screw designated generally by reference numeral 20. Bone screw 20 includes a lower threaded portion 220 for fastening the screw to the spinous process, an intermediate shank portion 222 having a smooth outer surface which tapers radially outwardly from the circumference of the lower threaded portion 220, and an upper body portion 224. Threaded portion 220 of bone screw 20 is provided with a helical thread designed to easily penetrate and securely engage the bone to fix the longitudinal rods 12 and 14 with respect to the vertebrae. The upper body portion 224 of bone screw 20 is defined by a base 226 and a pair of opposed upstanding side walls 228 and 230 which define a linear channel 282 therebetween. A hemicylindrical channel 232 is formed in the base 226 of body portion 224 for accommodating the lower portion of an elongated spinal rod 12, 14 received by the body portion 224.

With continuing reference to Fig. 10, bone screw 20 is provided with a locking member 100 which, as discussed hereinabove with reference to Fig. 5, includes a

pair of laterally opposed tapered wedges 116 and 118 configured to linearly engage correspondingly configured slots 236 and 238 defined in the upstanding side walls 228 and 230 of body portion 224 (see Fig. 12). As described hereinabove with respect to Fig. 5, the upper portion 114 of locking member 100 includes a provisional securement mechanism consisting of laterally opposed spaced apart paired retention ports 132, 134 and 136, 138, which are dimensioned and configured to receive and securely retain corresponding spaced apart paired engagement tabs 242, 244 and 246, 248 which project into the linear channel 282 from the opposed upstanding side walls 228 and 230 (see Fig. 12). As discussed hereinabove, the lower portion 112 of locking member 100 includes a hemi-cylindrical channel 120 extending along the longitudinal axis thereof. When used in conjunction with bone screw 20, channel 120 accommodates the upper portion of the spinal rod with which bone screw 20 is associated. Thus, it can be appreciated that preferably the same locking member configuration can be used to secure the bone screw and the connector to the spinal rods 12, 14.

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As discussed hereinabove with reference to Fig. 1, in addition to the connective device 30 and bone screws 20, stabilization system 10 also includes hooks 18 for facilitating segmental attachment of spinal rods 12 and 14 to different areas of the spinous process in conjunction with bone screws 20. Because the spine features different laminar geometries, spinal hooks are available in a variety of different configurations including for example, up angled hooks, down angled hooks, pedicle hooks, and neutral hooks.

The spinal hooks 18 which are illustrated in Fig. 1 are configured as lamina hooks and are provided with a locking member 100. The locking member for securing the hooks to the spinal rods is identical to the aforedescribed locking member for the bone screw 20. Locking member 100 linearly engages a corresponding linear channel formed in

the upper body of the lamina hook, in the same manner as in connector device 30 and bone screw 20, so as to secure the hook to the spinal rod with which it is associated. (The upper body portion of the hook is identical to the upper body portion 224 of bone screw 20 and therefore is not illustrated in detail.) In accordance with the subject application, it should be understood that locking member 100 can also be employed with up angled hooks, down angled hooks, neutral hooks and other configurations for securement to the spine. Thus, as noted above, each component of the spinal stabilization system disclosed herein and illustrated in Figs. 1 through 3 preferably utilizes identically configured locking members. Also, because the tapered wedges of the locking members are configured for linear engagement, undesirable torsional forces normally encountered with threaded components are not applied to the spine during implantation. Also, the linear sliding locking of the locking member provides uniform locking forces and avoids insufficient tightening or overtightening associated with threaded components.

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Figure 1 also illustrates one of the connector devices 30 positioned to straddle spinal hook 18. That is, since the distance between the rod engaging clips 58, 88, 60 and 90 exceeds the width/diameter of the fastener (e.g. hook 18 and bone screw 20), and the base 46, 66 is spaced a sufficient distance from the rod engaging clips, sufficient room is created so that the clips 58, 88 and 60, 90 can optionally be positioned on opposite sides of the hook 18 as shown. This reduces the longitudinal space on the spinal rods 12 and 14 occupied by the components of the stabilization system. The connector 30 can similarly is positioned to span the head of the bone screw 20.

During a spinal stabilization procedure, once the parallel spinal rods 12 and 14 have been securely fastened along either side of the spinous processes, the stabilization system 10 can be significantly strengthened by transversely linking the two spinal rods 12 and 14 to one another with one or more of the connective devices 30. To accomplish

transverse rod linking, the first connector 32 of connector device 30 is attached to spinal rod 12 by orienting the spaced apart arms 48 and 50 of yoke 44 so that the spinal rod 12 is disposed within the gap 49 defined therebetween. Connector 32 is then rotated relative to the spinal rod 12, utilizing a surgical instrument, in such a manner so as to cause the opposed arcuate engagement clips 58 and 60 to positively engage spinal rod 12 by spreading around the spinal rod through diametrical expansion. At such a time, the elongated connective beam 52 of connector 32 extends from spinal rod 12, across the spinous process, in such a manner so that the plane defined by the lower surface 52b of connective beam 52 is aligned with the longitudinal axis of spinal rod 12, contributing to the low-profile construction of the device. In other words, when connected, the connective beam 52 and longitudinal spinal rods 12 and 14 lie in substantially the same plane.

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Thereafter, the second connector 34 is attached to spinal rod 14 in a similar manner by orienting the spaced apart arms 68 and 70 of yoke 64 so that the spinal rod 14 is disposed within the gap defined therebetween. Connector 34 is then rotated relative to the spinal rod 14, preferably utilizing a surgical instrument, in such a manner so as to cause the opposed arcuate engagement clips 88 and 90 to positively engage spinal rod 14 by spreading around the spinal rod through diametrical expansion. Thereupon, the reception portion 72 projects transversely from spinal rod 14, in such a manner so as to receive the elongate connective beam 52 within reception channel 82, as shown, for example, in Fig. 6. Thus, the beam 52 can be placed between the walls 78 and 80 into the channel 82.

At such a time, the relative positions of the connective beam 52 and the reception channel 82 are properly set by the surgeon, either through rotation of the connectors 32 and 34 about the axes of spinal rods 12 and 14, respectively, or through cutting 52 to the desired length, as shown, for example, in Fig. 7. Locking member 100 is then linearly inserted into reception channel 82 in such a manner so that the opposed

tapered wedges 116 and 118 linearly engage the correspondingly configured tapered slots 126 and 128, as shown, for example, in Fig. 8. Linear insertion is continued until such time as the tapered wedges 116, 118 and tapered slots 126, 128 are fully engaged as shown, for example, in Fig. 9. Thereupon, connective beam 52 is securely fastened within reception channel 82 forming a low-profile stable bridge between spinal rods 12 and 14. As illustrated in Figs. 1 through 3, additional connective devices can be installed to further stabilize apparatus 10.

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It should be appreciated that Fig. 1 illustrates the spinal stabilization system with three connecting devices, four hooks and two bone screws by way of example. Clearly, fewer or more of the components can be utilized to construct the stabilization system.

In an alternate embodiment illustrated in Figure 13, a rod connector device is provided having a integral transverse rod or connective beam 502 as in the embodiment of Figure 4. However, this connector 500 is designed to be used with the connector 504 which is identical to clip 10E illustrated in Figure 15 of pending patent application serial no. 08/856,916, filed May 15, 1997, the contents of which are incorporated herein by reference. This transverse connector system of Figure 13 requires fewer components than the system of Figures 15 and 16 of application 08/856,916 because the connective beam 502 extends integrally from one of the connecting devices. When assembled, semi-circular beam 502 lies in a plane parallel (and above as viewed in Figure 13) to the plane of the longitudinal spinal rods 12 and 14. The semi-circular beam (rod) 502, however produces a lower profile than a system having a transverse circular rod. Connector 506 has arms 508, 510 and is clamped onto the longitudinal rod in the same manner as connector 32 of Figures 1-9.

Although the apparatus disclosed herein has been described with respect to preferred embodiments, it is apparent that modifications and changes can be made thereto without departing from the spirit and scope of the invention as defined by the claims.

\* \* \* \* \*

#### **WHAT IS CLAIMED IS:**

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1. Apparatus for connecting spaced apart spinal rods to one another comprising:

- a) a first connector configured to engage a first spinal rod at a location
   5 along the length thereof and including an elongated connective beam extending in a direction transverse to the first spinal rod;
  - b) a second connector configured to engage a second spinal and including a reception portion projecting in a direction transverse to the second spinal rod and defining a linear channel for receiving the elongated connective beam of the first connector; and
  - c) a locking member dimensioned and configured to linearly engage the channel and secure the position of said elongated connective beam with respect to said second connector.
- 2. Apparatus as recited in Claim 1, wherein the first connector includes a pair of opposed spaced apart arcuate engaging members configured to engage the first spinal rod and the second connector includes a pair of opposed spaced apart arcuate engaging members configured to engage the second spinal rod.
- 20 3. Apparatus as recited in Claim 2, wherein the first connector defines a yoke portion which includes a pair of opposed spaced apart arms, each of the spaced apart arms having an arcuate engaging member associated therewith.

4. Apparatus as recited in Claim 2, wherein the second connector defines a yoke portion which includes a pair of opposed spaced apart arms, each of the spaced apart arms having an arcuate engaging member associated therewith.

- 5. Apparatus as recited in Claim 1, wherein the linear channel is defined by a base portion having a planar surface and a pair of opposed spaced apart upstanding walls.
- Apparatus as recited in Claim 5, wherein the elongated connective beam has
  a semi-circular transverse cross-section, a lower surface thereof being planar and an upper
   surface thereof being curved.
  - 7. Apparatus as recited in Claim 6, wherein the planar lower surface of the elongated connective beam is configured to contact the planar surface of the base portion of the linear channel.

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8. Apparatus as recited in Claim 6, wherein the locking member includes a lower surface having a hemi-cylindrical channel for accommodating the upper surface of the elongated connective beam.

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9. Apparatus as recited in Claim 5, wherein the locking member includes an upper body portion having opposed leading and trailing ends, opposed lateral sides, and a pair of retention ports located on each of the lateral sides, the retention ports on each lateral side being spaced from one another at locations adjacent the leading and trailing ends of the upper body portion.

10. Apparatus as recited in Claim 9, wherein the opposed spaced apart upstanding walls of the channel each include an interior surface having a pair of spaced apart locking tabs for engaging a pair of corresponding spaced apart retention ports of the locking member.

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- 11. Apparatus as recited in Claim 5, wherein the locking member includes a lower body portion defining a pair of laterally opposed tapered wedges.
- 12. Apparatus as recited in Claim 11, wherein the opposed spaced apart upstanding walls of the channel each include an interior surface having a pair of tapered slots for receiving and engaging the pair of laterally opposed tapered wedges.
  - 13. A connecting member for connecting a transverse spinal rod to a longitudinal spinal rod comprising a base portion, a pair of spaced apart arcuate engaging members extending in a first direction from the base portion to engage the longitudinal spinal rod, and a pair of upstanding walls extending in a direction transverse to the first direction and forming a channel therebetween to receive the transverse spinal rod.
  - 14. A connecting member as recited in Claim 13, wherein the channel is configured to linearly receive a locking member to secure the transverse spinal rod within the channel.
  - 15. A connecting member as recited in Claim 14, wherein the channel has a base portion having a planar surface to receive a lower planar surface of the transverse spinal rod.

16. A connecting member as recited in Claim 14, wherein the upstanding walls of the channel each include an interior surface having a pair of spaced apart locking tabs for engaging a pair of corresponding spaced apart retention ports of the locking member.

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17. A connecting member as recited in Claim 16, wherein the opposed spaced apart upstanding walls of the channel each include an interior surface having a pair of tapered slots for engaging the pair of laterally opposed tapered wedges.

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longitudinal spinal rod comprising a base portion, a pair of upstanding walls extending from the base portion forming a channel to receive a transverse spinal rod in a first plane, and a pair of arcuate engaging members extending from the base portion to engage the longitudinal rod in substantially the same plane as the first plane.

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19. A connecting member as recited in Claim 18, wherein the bottom surface of the base portion of the channel is planar and configured to a contact a planar lower surface of the transverse rod.

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20. A connecting member as recited in Claim 18, wherein the channel is configured to linearly receive a locking member to retain the transverse spinal rod within the channel.

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21. A connecting member as recited in Claim 20, wherein the upstanding walls of the channel each include an interior surface having a pair of spaced apart locking tabs for engaging a pair of corresponding spaced apart retention ports of the locking member.

- 5 22. A connecting member as recited in Claim 21, wherein the opposed spaced apart upstanding walls of the channel each include an interior surface having a pair of tapered slots for engaging the pair of laterally opposed tapered wedges.
- 23. A connecting member as recited in Claim 18, wherein the arcuate engaging members are oppositely facing mirror images of one another.
  - 24. A connecting member for connecting a transverse spinal rod to a longitudinal spinal rod, the longitudinal rod connected to the spine by at least one fastener, the connecting member comprising first and second spaced apart engaging members configured to engage the longitudinal rod, the engaging members spaced apart a first distance grater than a width of the fastener such that the fastener is positioned between the first and second engaging arms of the connecting member.
- 25. A connecting member as recited in claim 24, further comprising an elongated connective beam extending integrally from the connecting member.
  - 26. System for spinal stabilization comprising:

- a) a first elongated spinal rod;
- b) a second elongated spinal rod;

c) at least one fastening device for securing the first elongated spinal rod to a first side of the spinous process;

- d) at least one fastening device for securing the second elongated spinal rod to a second side of the spinous process in spaced relationship to the first spinal rod;
- e) a first connector configured to engage the first spinal rod at a location along the length thereof and including an elongated connective beam having an axis extending in a direction transverse to the first spinal rod;
  - f) a second connector configured to engage the second spinal rod at a location adjacent the first connector and including a reception portion projecting in a direction transverse to the second spinal rod and defining a linear channel for receiving the elongated connective beam of the first connector; and
  - g) a locking member dimensioned and configured to linearly engage the channel along the axis of the connective beam and secure the longitudinal position of the connective beam with respect to the second connector so as to transversely connect the first and second spinal rods to one another.
  - 27. System as recited in Claim 26, wherein the first and second fastening devices are selected from the group consisting of hooks and screws.

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28. System as recited in Claim 27, wherein the hooks and screws each include linear reception channels for accommodating the spinal rods, and the hooks and screws are secured to the spinal rods by respective locking members which linearly engage the reception channels of the hooks and screws along the longitudinal axis of the spinal rod associated therewith.

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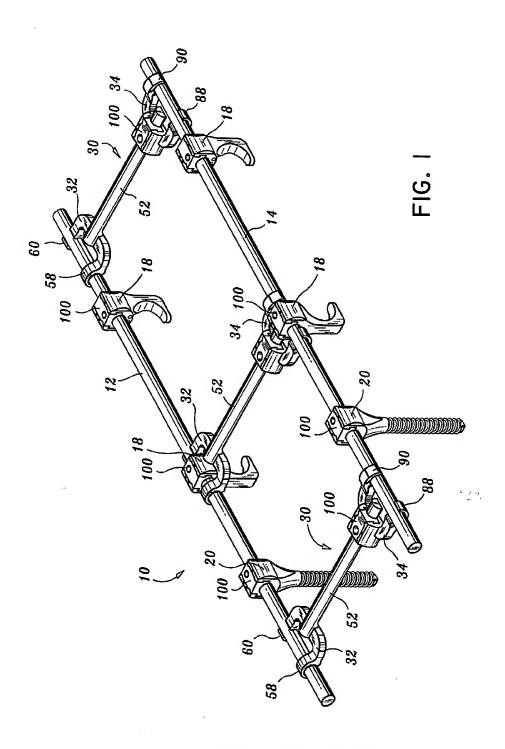
29. System as recited in Claim 26, wherein the first connector includes a pair of opposed spaced apart arcuate engaging members configured to engage the first spinal rod and the second connector includes a pair of opposed spaced apart arcuate engaging members configured to engage the second spinal rod.

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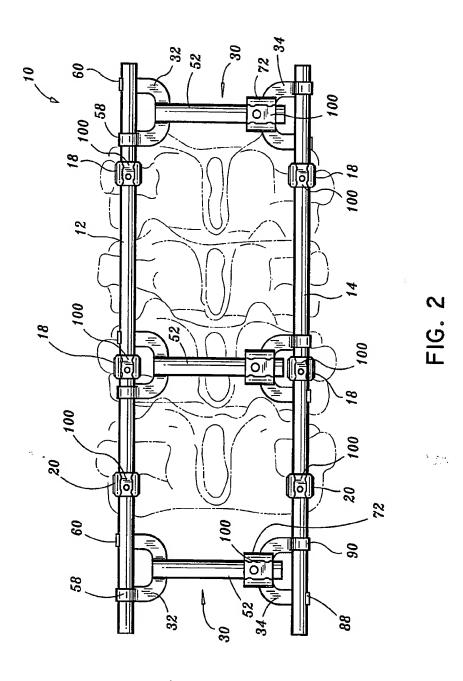
- 30. System as recited in Claim 29, wherein the first connector defines a yoke portion which includes a pair of opposed spaced apart arms, each of the spaced apart arms having an arcuate engaging member associated therewith.
- 31. Apparatus as recited in Claim 29, wherein the second connector defines a yoke portion which includes a pair of opposed spaced apart arms, each of the spaced apart arms having an arcuate engaging member associated therewith.

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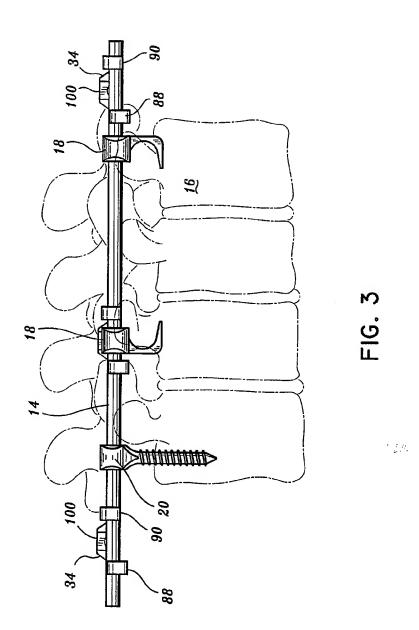
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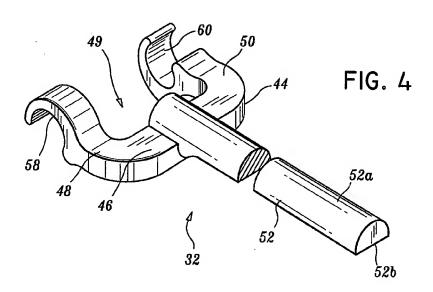


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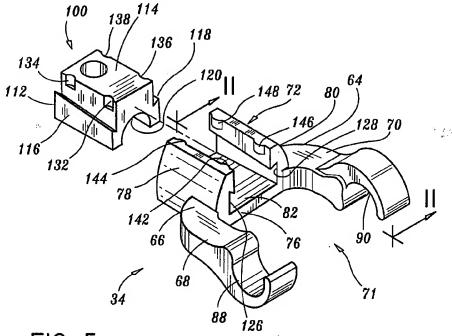
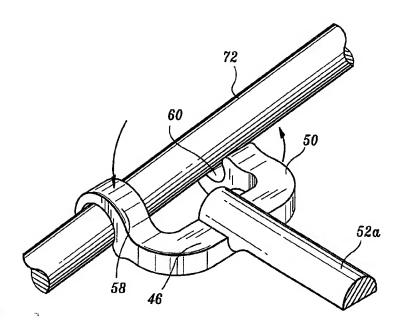


FIG. 5

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FIG. 4A



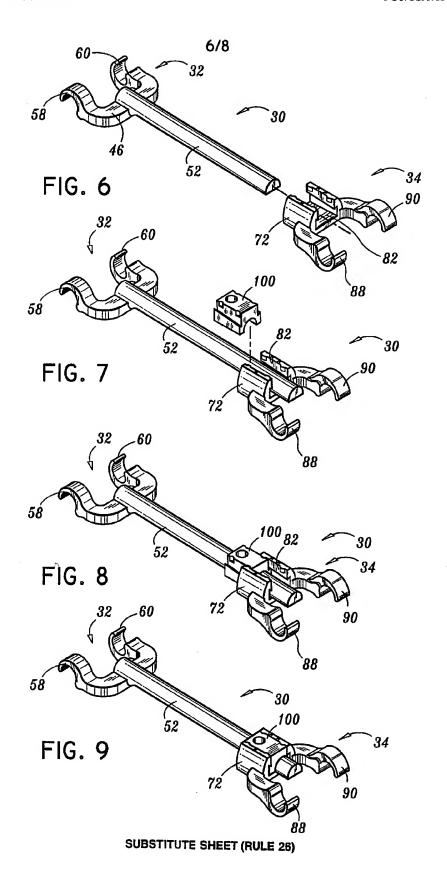
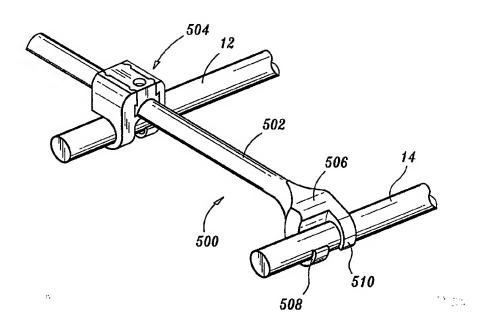


FIG. 13



## INTERNATIONAL SEARCH REPORT

International application No. PCT/US99/13487

A. CLAS	SSIFICATION OF SUBJECT MATTER							
	A61B 17/70							
US CL :	606/61  o International Patent Classification (IPC) or to both t	national classification and IPC						
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Documentat	ion searched other than minimum documentation to the	extent that such documents are included	in the fields searched					
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C. DOC	UMENTS CONSIDERED TO BE RELEVANT							
Category*	Citation of document, with indication, where ap	propriate, of the relevant passages	Relevant to claim No.					
Х	US 5,439,463 A (LIN) 08 August 199	5, Figs. 4a and 4b.	1-5, 13-15, 18-20,					
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			24-31					
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Y	US 5,380,326 A (LIN) 10 January 199	35, Figs. 1, 1a and 5.	20-20					
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Y	US 5,562,663 A (WISNEWSKI et al) 08 October 1996, Figs. 2-15. 26-28							
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Further documents are listed in the continuation of Box C. See patent family annex.								
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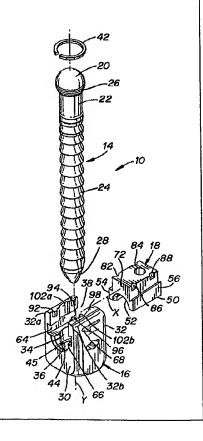
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(30) Priority Data: 09/098,927 17 June 1998 (17.06.98)	ţ	Published  With international search report.
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#### (54) Title: DEVICE FOR SECURING SPINAL RODS

## (57) Abstract

A device is disclosed for securing a spinal rod to the spine comprising a fastener having a curvate head portion, a securement body having an interior cavity including a first portion having a first axis and configured to accommodate the curvate head portion of the fastener and a second portion having a second axis and configured to accommodate a spinal rod in such a manner so that the spinal rod and the curvate head portion are in contact with one another, and a locking member configured to linearly engage the second portion of the interior cavity of the securement body along the axis thereof in such a manner so as to secure the relative position of the spinal rod and the head portion of the fastener.



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#### **DEVICE FOR SECURING SPINAL RODS**

## **BACKGROUND OF THE INVENTION**

#### 1. Field of the Invention

The subject disclosure relates to implantable spinal stabilization systems for surgical treatment of spinal disorders, and more particularly, to a device for securing a cylindrical spinal rod of a spinal stabilization system to the spine.

#### 2. Background of the Related Art

The spinal column is a complex system of bones and connective tissue which protects critical elements of the nervous system. Despite these complexities, the spine is a highly flexible structure, capable of a high degree of curvature and twist through a wide range of motion. Trauma or developmental irregularities can result in spinal pathologies which limit this range of motion.

For many years, orthopedic surgeons have attempted to correct spinal irregularities and restore stability to traumatized areas of the spine through immobilization. Over the past ten years, spinal implant systems have been developed to achieve immobilization. Examples such systems are disclosed in U.S. Patent Nos. 5,102,412 and 5,181,917. Such systems often include spinal instrumentation having connective structures such as elongated rods which are placed on opposite sides of the portion of the spinal column intended to be immobilized. Screws and hooks are commonly utilized to facilitate segmental attachment of such connective structures to the posterior surfaces of the spinal laminae, through the pedicles, and into the vertebral bodies. These components provide the necessary stability both in tension and compression.

It has been recognized that considerable difficulty is associated with inserting screws along a misaligned spinal curvature and simultaneously positioning coupling elements in alignment with a cylindrical spinal rod having a fixed axis without distorting the screws. Many attempts have been made in the prior art to provide instrumentation which permit angulation of a screw relative to the coupling elements of a spinal rod. Examples of such devices are disclosed in U.S. Patent Nos. 5,549,608, 5,554,157 and 5,690,630. However, these prior art devices are connected to the spinal rod by threaded components that necessarily require the application of undesirable torsional forces to the spine. Furthermore, these threaded components can loosen under cyclically applied loads commonly encountered in the spinal column. Clearly, it would be beneficial to provide an improved device for securing spinal rods to the spinous process which provides a wide range of angular adjustability, uniform securement and which does not require the application of undesirable torsional forces during application.

#### 15 SUMMARY OF THE DISCLOSURE

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The subject disclosure is directed to a device for securing a spinal rod to the spine during a spinal stabilization procedure. The device includes a fastener having a head portion and body portion which depends from the head portion and has a longitudinal axis which extends therethrough. The device further includes a securement body having an interior cavity which includes a lower portion having a first axis and is configured for accommodating pivotal movement of the head portion of the fastener in such a manner so as to permit selective orientation of the longitudinal axis of the body portion of the fastener relative to the first axis of the lower portion of the interior cavity. Preferably the head portion of the fastener is curvate in configuration.

The interior cavity of the securement body further includes an upper portion having a second axis which extends perpendicular to the first axis and defines an elongate channel to accommodate a spinal rod. Preferably, the cylindrical spinal rod and the curvate head portion are in contact with one another at a location on the first axis. The device further includes a locking member configured to linearly engage the upper portion of the interior cavity of the securement body along the second axis in such a manner so as to secure the relative position of the cylindrical spinal rod and the curvate head portion and thereby fix the selected orientation of the longitudinal axis of the body portion of the fastener relative to the first axis.

Preferably, the upper portion of the interior cavity includes opposed recess areas for accommodating insertion of the head portion into the interior cavity of the securement body. In addition, the lower portion of the interior cavity of the securement body preferably includes an annular retention channel for accommodating a retaining ring in a position circumscribing the curvate head portion of the threaded fastener, and a split retaining ring is provided which is dimensioned and configured for reception within the annular retention channel.

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Preferably, the locking member of the rod securing device includes a lower portion having a hemi-cylindrical channel defined therein for accommodating an upper portion of the cylindrical spinal rod. In addition, the lower portion of the locking member preferably includes a pair of laterally opposed tapered wedges dimensioned and configured to lockingly engage a corresponding pair of laterally opposed tapered slots defined in the securement body within the upper portion of the interior cavity. The locking member also preferably includes an upper portion having laterally opposed pairs of spaced apart reception ports dimensioned and configured to lockingly engage laterally opposed pairs of

spaced apart locking tabs projecting from the securement body within the second portion of the interior cavity thereof.

Because the tapered wedges of the locking member engage the slots of the reception channel linearly along the axis of the cylindrical spinal rod, the application of undesirable torsional forces to the spine normally generated during the process of tightening a conventional threaded component is avoided. Furthermore, while threaded components can loosen under cyclically applied loads commonly encountered in the spinal column, the locking member remains fixed under such conditions.

These and other features of the device disclosed herein and the method of installing the same will become more readily apparent from the following description of the drawings.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

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So that those having ordinary skill in the art to which the disclosed device appertains will more readily understand how to construct and use the same, reference may be had to the drawings wherein:

Fig. 1 is a perspective view of a device for securing a cylindrical spinal rod to the spinous process constructed in accordance with a preferred embodiment of the subject disclosure;

- Fig. 2 is an exploded perspective view of the device illustrated in Fig. 1 with each of the components parts thereof separated for ease of illustration;
- Fig. 3 is a cross-sectional view taken along line 3-3 of Fig. 1 illustrating the interaction between a cylindrical spinal rod and the curvate head of the fastener;
- Fig. 4 is a cross-sectional view taken along line 4-4 of Fig. 1 illustrating the interaction between the linear locking member and the cylindrical spinal rod; and

Fig. 5 is a perspective view of the curvate head portion of another threaded fastener constructed in accordance with the subject disclosure; and

Fig. 6 is a cross-sectional view similar to that of Fig. 3 illustrating the interaction between the cylindrical spinal rod and the head portion of the fastener illustrated in Fig. 5.

These and other features of the rod securement device disclosed herein will become more readily apparent to those having ordinary skill in the art from the following detailed description of the invention taken in conjunction with the drawings.

#### 10 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

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Referring now to the drawings wherein like reference numerals identify similar structural elements of the disclosed device, there is illustrated in Fig. 1 a rod securement device constructed in accordance with a preferred embodiment of the subject disclosure and designated generally by reference numeral 10. As illustrated in Fig. 1, securement device 10 is employed in conjunction with an elongated cylindrical spinal rod 12 and is configured to secure longitudinal spinal rod 12 to the spine during a spinal stabilization procedure.

Referring now to Figs. 1 and 2, rod securement device 10 includes a fastener 14, a securement body 16 and a locking member 18. Fastener 14 includes a curvate head portion 20, a generally cylindrical neck portion 22 which depends from the curvate head portion 20, and an elongated threaded body portion 24 which depends from the cylindrical neck portion 22. The outer surface of the curvate head portion 20 is continuous and preferably includes a series of circular ridges 26 extending about the lower hemisphere thereof, adjacent the annular neck portion 22. The threads of body portion 24 are particularly adapted to securely engage bone and define a continuous helix extending

about the longitudinal axis of body portion 24 from the pointed tip 28 of fastener 14 to the neck portion 22 thereof.

With continuing reference to Fig. 2, securement body 16 includes a lower body portion 30, an upper body portion 32 and an interior cavity 34. The interior cavity 34 of securement body 16 includes a lower cavity portion 36 defined within the lower body portion 30 of securement body 16 and an upper cavity portion 38 defined within the upper body portion 32 of securement body 16. The upper cavity portion 38 of interior cavity 34 has a first longitudinal axis designated "X" extending therethrough and the lower cavity portion 36 of interior cavity 34 has a second longitudinal axis designated "Y" extending therethrough which is perpendicular to the longitudinal axis of the upper cavity portion 38.

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As best seen in Figs 3 and 4, the lower cavity portion 36 of interior cavity 34 forms a seat for accommodating the curvate head portion 20 of fastener 14. More particularly, the lower cavity portion 36 of the interior cavity 34 of securement body 16 includes a curved surface area 40 configured for registration with the lower hemisphere of the curvate head portion 20, i.e., the section of curvate head portion 20 bearing circular ridges 26. Those skilled in the art will readily appreciate that the circular ridges provide an enhanced gripping area for the head portion 20. The curved surface area 40 of interior cavity 34 is designed to permit the selective orientation of the longitudinal axis of the threaded body portion 24 of fastener 14 relative to the longitudinal axis "Y" of the lower cavity portion 36 of interior cavity 34, as will be described in greater detail hereinbelow.

Referring back to Fig. 2, an annular channel 45 is formed in the lower body portion 30 of securement body 16 within the lower cavity portion 36 of the interior cavity 34 above the curved surface area 40 thereof. Annular channel 45 is configured to accommodate a split retaining ring 42 which is dimensioned to circumscribe the upper hemisphere of the curvate head portion 20 of fastener 14 (see Figs. 3 and 4). When the

lower hemisphere of the curvate head portion 20 of fastener 14 is in registration with the curved surface area 40 of interior cavity 34, retaining ring 42 positively retains the fastener 14 therein.

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The upper cavity portion 38 of interior cavity 34 is defined in part by a hemi-cylindrical passageway 44 which intersects a region of the lower cavity portion 36 of interior cavity 34 above annular channel 45. Passageway 44 is configured to accommodate the lower hemi-cylindrical portion of spinal rod 12 and is dimensioned such that when spinal rod 12 extends through securement body 16, spinal rod 12 and curvate head portion 20 are in abutting contact at a location lying on the longitudinal axis of the lower cavity portion 36 of interior cavity 34, as illustrated in Figs. 3 and 4. Moreover, at such a time a horizontal plane which extends tangent to the upper surface of the curvate head portion 22 is coplanar with a horizontal plane which extends tangent to the lower surface of the spinal rod 12.

Securement device 10 further includes a locking member 18 dimensioned and configured to linearly engage the upper cavity portion 38 of interior cavity 34 along the longitudinal axis "X" of the upper cavity portion 38 to positively secure the axial position of the securement body 16 with respect to spinal rod 12. Furthermore, when locking member 18 is linearly engaged in the upper cavity portion 38 of interior cavity 34, spinal rod 12 is urged against the curvate head portion 20 of fastener 14 in such a manner so as to fix the selected orientation of the longitudinal axis of the threaded body portion 24 of fastener 14. More particularly, locking member 18 includes a lower body portion 50 having a hemi-cylindrical channel 52 extending therethrough for accommodating the upper hemi-cylindrical portion of spinal rod 12 extending through the upper cavity portion 38 of interior cavity 34.

In addition, locking member 18 includes a locking mechanism in the form of a pair of laterally opposed tapered wedges 54 and 56 depending from either side of the lower body portion 50 of locking member 18 for engaging a corresponding pair of laterally opposed tapered slots 64 and 66 formed in the upper body portion 32 of securement body 16 within the upper cavity portion 38 of interior cavity 34. The tapered wedges 54, 56 and corresponding tapered slots 64, 66 employ inwardly angled sloping locking surfaces to effect positive engagement therebetween. An indicator arrow designated by reference numeral 68 is provided on the exterior surface of the upper body portion 32 of securement body 16 to indicate the proper direction in which to linearly engage locking member 18 in the upper cavity portion 38.

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With continuing reference to Fig. 2 in conjunction with Figs. 3 and 4, the upper body portion 72 of locking member 18 further includes a secondary securement mechanism consisting of laterally opposed paired retention ports 82, 84 and 86, 88. Laterally opposed retention ports 82 and 86 are disposed adjacent the leading end of locking member 18 while laterally opposed retention ports 84 and 88 are disposed adjacent the trailing end of locking member 18. The paired retention ports are dimensioned and configured to receive and securely retain corresponding paired engagement tabs 92, 94 and 96, 98 which project into the upper cavity portion 38 from the upper body portion 32 of securement body 16.

As best seen in Fig. 2, the interior surfaces of the side walls 32a and 32b of upper body portion 32 include curved recess 102a and 102b, respectively, for accommodating the passage of the curvate head portion 20 of fastener 14 when the fastener is inserted into the securement body 16 to seat the curvate head portion 20 within the lower cavity portion 36 of interior cavity 34.

Referring now to Figs. 3 and 4, during a spinal stabilization procedure, prior to engagement of the spinal rod 12 with the securement body 16 of securement device 10, the threaded fastener 14 is inserted into the interior cavity 34 of securement body 16 such that the curvate head portion 22 passes through curved recesses 102a and 102b and registers with curved surface area 40 defined within the lower cavity portion 36 of interior cavity 34. Thereupon, the split retaining ring 42 is inserted into the annular channel 45 formed within the lower cavity portion 36 to positively retain threaded fastener 14 therein.

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At such a time, the curvate head portion 22 of threaded fastener 14 is free to pivot within its seat in the lower cavity portion 36 about the longitudinal axis "Y" which extends therethrough. Consequently, the threaded body portion 24 of threaded fastener 14 may be selectively oriented at a desirable angle with respect to the longitudinal axis of the spinal rod 12 with which it is to become associated. Once the desired orientation of the threaded fastener 14 has been established, it is secured in place using conventional surgical instrumentation. At such a time, the securement body 16 is pivoted relative to the curvate head portion 22 of threaded fastener 14 so that the cylindrical rod 12 is received within passageway 44. Thereupon, the cylindrical spinal rod 12 and the curvate head portion 22 of threaded fastener 14 are in abutting contact at a location lying on the longitudinal axis of the lower cavity portion 36 of interior cavity 34.

Then, locking member 18 is linearly inserted into the upper cavity portion

38 of interior cavity 34 in the direction shown by indicator arrow 68 such that laterally opposed tapered wedges 54 and 56 depending from either side of the lower body portion 50 of locking member 18 engage the laterally opposed tapered slots 64 and 66 formed in the upper body portion 32 of securement body 16. Provisional locking of the locking member 18 within the upper cavity portion further 38 is provided by the engagement of the laterally opposed paired retention ports 82, 84 and 86, 88 formed in the upper body portion

72 of locking member 18 with the corresponding paired engagement tabs 92, 94 and 96, 98 which project into the upper cavity portion 38 from the interior surfaces of the side walls 32a and 32b of securement body 16. This provisional locking maintains the locking member 18 in place until it is finally locked upon engagement of the tapered wedges 54, 56 and tapered slots 64, 66.

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Once the locking member 18 has been fully engaged in upper cavity portion 38, the geometric configuration and dimensional characteristics thereof function to urge the cylindrical spinal rod 12 into close approximation with the curvate head portion 22 of threaded fastener 14. In essence, linear engagement of the locking member 18 along the longitudinal axis of cylindrical spinal rod 12 compresses the entire mechanical construct so that the relative position of the longitudinal spinal rod 12 and the curvate head portion 22 becomes fixed, as does the relative position of the curvate head portion 22 and the curved surface 40 of lower cavity portion 36.

Referring now to Figs 5 and 6, there is illustrated another threaded fastener constructed in accordance with the subject disclosure and designated generally by reference numeral 114. Threaded fastener 114 includes a curvate head portion 122 which has a discontinuous curvate surface. More particularly, the curvate head portion 122 of threaded fastener 114 is defined by a curvate upper polar region 122a, four circumferentially spaced apart longitudinal arc portions 122b through 122e, and a curvate lower polar region 122f which includes a series of circular ridges 126 for interacting with the curved scating surface 40 defining the lower cavity portion 36 of securement body 16. The construction of the curvate head portion 122 of threaded fastener 114 facilitates placement as the tool can more easily grip the head of the shaft for driving or adjusting the fastener. As best seen in Fig. 6, in operation, the cylindrical spinal rod 16 is in abutting contact with the curvate upper polar region 122a of the curvate head portion 122 of threaded fastener 114.

Although the device disclosed herein has been described with respect to preferred embodiments, it is apparent that modifications and changes can be made thereto without departing from the spirit and scope of the invention as defined by the claims.

#### WHAT IS CLAIMED IS:

- 1. A device for securing a spinal rod to the spine comprising:
  - a) a fastener having a head portion;
- b) a securement body having an interior cavity including a first portion having a first axis and configured to accommodate the head portion of the fastener and a second portion having a second axis and configured to accommodate a spinal rod; and
  - c) a locking member configured to linearly engage the second portion of the interior cavity of the securement body along the axis thereof in such a manner so as to secure the relative position of the spinal rod and the head portion of the fastener.

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- 2. A device as recited in Claim 1, wherein the head portion is curvate in configuration.
- 3. A device as recited in Claim 2, wherein the curvate head portion of the fastener defines a continuous curvate surface.
  - 4. A device as recited in Claim 2, wherein the curvate head portion of the fastener defines a discontinuous curvate surface.
- 5. A device as recited in Claim 1, wherein the spinal rod and head portion are positioned in contact with one another within the interior cavity.
  - 6. A device as recited in Claim 1, wherein the first axis extends perpendicular to the second axis.

7. A device as recited in Claim 6, wherein the head portion and the spinal rod contact at a location aligned with the first axis.

- 8. A device as recited in Claim 2, wherein the first portion of the interior
  5 cavity includes a curvate seat configured to register with the curvate head portion of the fastener.
- 9. A device as recited in Claim 1, wherein the first portion of the interior cavity of the securement body includes an annular retention channel for accommodating a
   retaining ring in a position circumscribing the head portion of the fastener.
  - 10. A device as recited in Claim 9, further comprising a split retaining ring dimensioned and configured for reception within the annular retention channel in the first portion of the interior cavity of the securement body.

- 11. A device as recited in Claim 1, wherein the locking member includes a lower portion having a channel defined therein for accommodating an upper portion of the spinal rod.
- 20 12. A device as recited in Claim 11, wherein the lower portion of the locking member includes a pair of laterally opposed tapered wedges dimensioned and configured to lockingly engage a corresponding pair of laterally opposed tapered slots defined in the securement body within the second portion of the interior cavity.

13. A device as recited in Claim 12, wherein the locking member includes an upper portion having laterally opposed pairs of spaced apart reception ports dimensioned and configured to lockingly engage laterally opposed pairs of spaced apart locking tabs projecting from the securement body within the second portion of the interior cavity.

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- 14. A device for securing a spinal rod to the spine comprising:
  - a) a fastener having a head portion;
- b) a securement body having an interior cavity including a first portion having a first axis and defining a seat for accommodating the head portion of the fastener in such a manner so as to permit the pivotal movement thereof relative to the first axis, and a second portion having a second axis and defining an elongate channel to accommodate a spinal rod; and
- c) a locking member configured to linearly engage the second portion of the interior cavity of the securement body along the axis thereof in such a manner so as to secure the relative position of the spinal rod and the head portion.
- 15. A device as recited in Claim 14, wherein the head portion of the fastener defines a continuous curvate surface.
- 20 16. A device as recited in Claim 14, wherein the head portion of the fastener defines a discontinuous curvate surface.
  - 17. A device as recited in Claim 14, wherein the first axis extends perpendicular to the second axis.

18. A device as recited in Claim 17, wherein the head portion and the spinal rod contact one another at a location on the first axis.

- 19. A device as recited in Claim 14, wherein the first portion of the interior cavity of the securement body includes an annular retention channel for accommodating a retaining ring in a position circumscribing the head portion of the fastener.
  - 20. A device as recited in Claim 19, further comprising a split retaining ring dimensioned and configured for reception within the annular retention channel in the first portion of the interior cavity of the securement body.
  - 21. A device as recited in Claim 14, wherein the locking member includes a lower portion having a hemi-cylindrical channel defined therein for accommodating an upper portion of the cylindrical spinal rod.

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22. A device as recited in Claim 21, wherein the lower portion of the locking member includes a pair of laterally opposed tapered wedges dimensioned and configured to lockingly engage a corresponding pair of laterally opposed tapered slots defined in the securement body within the second portion of the interior cavity.

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23. A device as recited in Claim 21, wherein the locking member includes an upper portion having laterally opposed pairs of spaced apart reception ports dimensioned and configured to lockingly engage laterally opposed pairs of spaced apart locking tabs projecting from the securement body within the second portion of the interior cavity.

24. A device for securing a cylindrical spinal rod to the spine comprising:

a) a fastener having a curvate head portion and an elongated threaded body portion depending from the curvate head portion and having a longitudinal axis extending therethrough;

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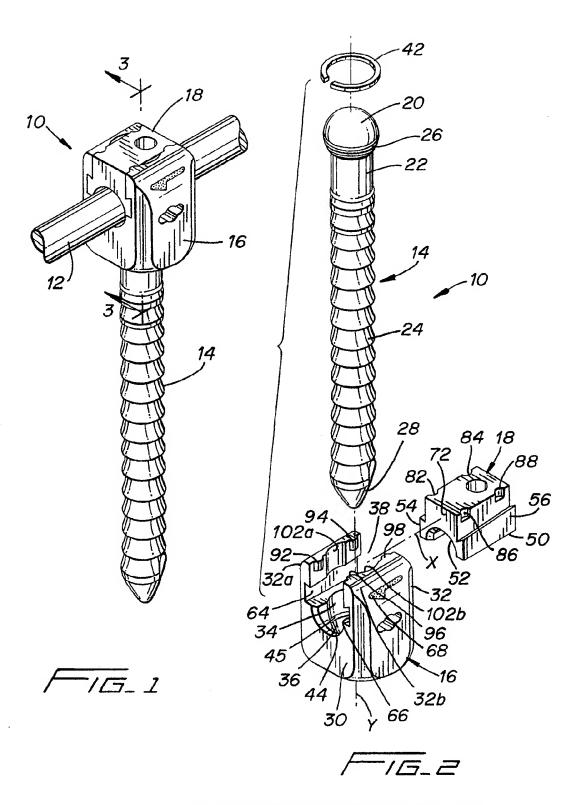
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- b) a securement body having an interior cavity including a first portion having a first axis and defining a curvate seat for accommodating pivotal movement of the curvate head portion in such a manner so as to permit selective orientation of the longitudinal axis of the threaded body portion of the fastener relative to the first axis, and a second portion having a second axis extending perpendicular to the first axis and defining an elongate channel to accommodate a cylindrical spinal rod in such a manner so that the cylindrical spinal rod and the curvate head portion are contact with one another at a location aligned with the first axis; and
- c) a locking member configured to linearly engage the second portion of the interior cavity of the securement body along the second axis in such a manner so as to secure the relative position of the cylindrical spinal rod and the curvate head portion to fix the selected orientation of the longitudinal axis of the threaded body portion of the fastener relative to the first axis.
- 25. A device as recited in Claim 24, wherein the curvate head portion of the fastener defines a continuous curvate surface.
  - 26. A device as recited in Claim 24, wherein the curvate head portion of the fastener defines a discontinuous curvate surface.

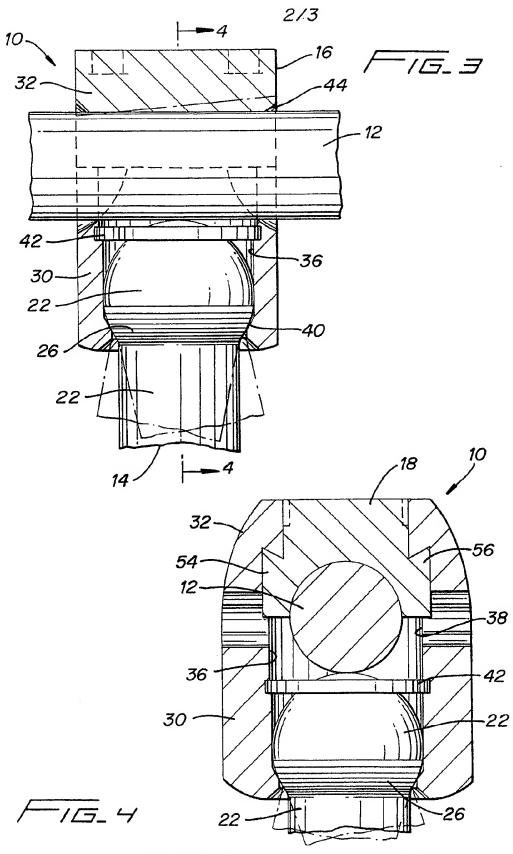
27. A device as recited in Claim 24, wherein the first portion of the interior cavity of the securement body includes an annular retention channel for accommodating a retaining ring in a position circumscribing the curvate head portion of the threaded fastener.

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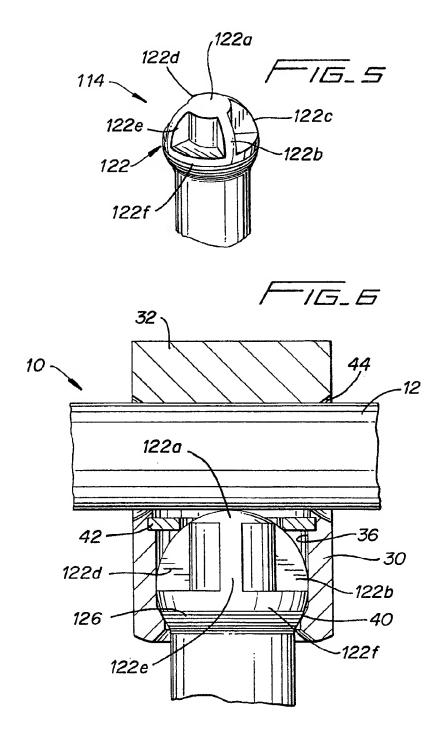
- 28. A device as recited in Claim 27, further comprising a split retaining ring dimensioned and configured for reception within the annular retention channel in the first portion of the interior cavity of the securement body.
- 10 29. A device as recited in Claim 24, wherein the locking member includes a lower portion having a hemi-cylindrical channel defined therein for accommodating an upper portion of the cylindrical spinal rod.
- 30. A device as recited in Claim 29, wherein the lower portion of the locking member includes a pair of laterally opposed tapered wedges dimensioned and configured to lockingly engage a corresponding pair of laterally opposed tapered slots defined in the securement body within the second portion of the interior cavity.
- 31. A device as recited in Claim 29, wherein the locking member includes an upper portion having laterally opposed pairs of spaced apart reception ports dimensioned and configured to lockingly engage laterally opposed pairs of spaced apart locking tabs projecting from the securement body within the second portion of the interior cavity.



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Inte 'ional Application No PCT'/US 99/13510

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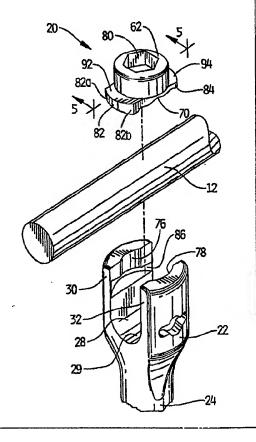
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(30) Priority Data: 09/167,439 6 October 1998 (06.10.98)  (71) Applicant: SURGICAL DYNAMICS, INC. [US/U	US]; 1	Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of
Glover Avenue, Norwalk, CT 06856 (US).  (72) Inventor: YUAN, Hansen; 5066 Pine Valley Drive teville, NY 13066 (US).		
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## (54) Title: DEVICE FOR SECURING SPINAL RODS

#### (57) Abstract

A device is disclosed for securing a spinal rod to the spine which includes a head portion configured to receive a spinal rod, a locking cap configured to engage the head portion and the spinal rod upon rotation of the locking cap relative to the head portion to secure the position of the head portion relative to the spinal rod, and a fastener portion depending from the head portion and configured to engage the spine.



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CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Suđan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

## **DEVICE FOR SECURING SPINAL RODS**

#### **BACKGROUND OF THE INVENTION**

#### 1. Field of the Invention

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The subject disclosure relates to implantable spinal stabilization systems

for surgical treatment of spinal disorders, and more particularly, to a device for
connecting cylindrical spinal rods of a spinal stabilization system to the spine.

#### 2. Background of the Related Art

The spinal column is a complex system of bones and connective tissue which protects critical elements of the nervous system. Despite these complexities, the spine is a highly flexible structure, capable of a high degree of curvature and twist through a wide range of motion. Trauma or developmental irregularities can result in spinal pathologies which limit this range of motion.

For many years, orthopedic surgeons have attempted to correct spinal irregularities and restore stability to traumatized areas of the spine through

20 immobilization. Over the past ten years, spinal implant systems have been developed to achieve immobilization. Examples of such systems are disclosed in U.S. Patent Nos.

5,102,412 and 5,181,917 to Rogozinski. Such systems often include spinal instrumentation having connective structures such as elongated rods which are placed on opposite sides of the portion of the spinal column intended to be immobilized. Screws

25 and hooks are commonly utilized to facilitate segmental attachment of such connective structures to the posterior surfaces of the spinal laminae, through the pedicles, and into

the vertebral bodies. These components provide the necessary stability both in tension and compression to achieve immobilization.

Various fastening mechanisms have been provided in the prior art to facilitate securement of screws and hooks to the connective structures of a spinal stabilization system. For example, U.S. Patent No. 5,257,993 to Asher discloses an apparatus for use in retaining a spinal hook on an elongated spinal rod. The apparatus includes a body extending upwardly from a hook portion and having an open ended recess for receiving a spinal rod and an end cap engageable with the body to close the recess. A set screw is disposed in the center of the end cap to clamp the rod in the recess of the body. The end cap and body are interconnectable by different types of connectors including a bayonet connector, a linear cam connector or a threaded connector. Other examples of fastening mechanism for facilitating attachment of screws and hooks to the connective structures of a spinal stabilization system are disclosed in U.S. Patent No. 5,437,669 to Yuan et al. and U.S. Patent No. 5,437,670 to Sherman et al.

In each of these prior art examples, threaded fasteners are used to facilitate securement of the connector to the spinal rod. Yet it is well known that threaded fasteners can become loosened under the influence of cyclically applied loads commonly encountered by the spinal column. Furthermore, during assembly, excessive torque applied to a threaded fastener can cause damage to the fastener as well as to the connective device with which it is associated.

It would be beneficial to provide a more reliable and effective mechanism for facilitating the attachment of screws, hooks and clamps to the connective structures of a spinal stabilization system.

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#### SUMMARY OF THE DISCLOSURE

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The subject disclosure is directed to a device for securing a spinal rod to a fixation device such as a pedicle screw or a lamina hook. The device disclosed herein includes a head portion configured to receive a spinal rod, a locking cap configured to engage the head portion and the spinal rod upon rotation of the locking cap relative to the head portion to secure the position of the head portion relative to the spinal rod, and a fastener portion extending from the head portion and configured to engage the spine. The fastener portion of the device can be in the form of a screw, hook or clamp, or any other configuration known in the art.

The head portion of the device has a channel extending therethrough for receiving a spinal rod and the channel is preferably bounded by opposed side walls each having an arcuate engagement slot defined therein. The locking cap preferably has opposed arcuate engagement flanges configured for reception in the opposed arcuate engagement slots of the head portion upon rotation of the locking cap relative to the head portion. Preferably, the opposed engagement slots are each defined in part by inclined slot surfaces, with the angle of the inclined surface of one engagement slot being opposite that of the opposed engagement slot. Similarly, the opposed engagement flanges are preferably each defined in part by inclined flange surfaces, with the angle of the inclined surface of one engagement flange being opposite that of the opposed engagement flange. The head portion also preferably includes structure for interacting with the locking cap to prevent the opposed side walls of the head portion from expanding radially outwardly when the arcuate flanges are engaged in the arcuate slots.

Preferably, the locking cap of the device is configured for rotation between an initial position in which the arcuate engagement flanges are 90° out of phase with the arcuate engagement slots, an intermediate position in which the arcuate engagement

flanges are 45° out of phase with the arcuate engagement slots, and a locked position in which the arcuate engagement flanges are in phase and intimately engaged with the arcuate engagement slots.

In this regard, the bottom surface of the locking cap preferably includes a first recess oriented to accommodate a spinal rod when the locking cap is in an initial unlocked position, a second recesses which intersects the first recess at a first angle to accommodate a spinal rod when the locking cap is in an intermediate position, and a third recess which intersects the elongate recess at a second angle to accommodate a spinal rod when the locking cap is in a final locked position. In accordance with a preferred embodiment of the subject disclosure, the first recess is an elongate recess, the second recess is a transverse recess which intersects the elongate recess at a 45° angle, and the third recess is an orthogonal recess which intersects the elongate recess at a 90° angle.

These and other unique features of the device disclosed herein and the method of installing the same will become more readily apparent from the following description of the drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

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So that those having ordinary skill in the art to which the disclosed apparatus appertains will more readily understand how to construct and use the same, reference may be had to the drawings wherein:

Fig. 1 is a perspective view of an elongated spinal rod of a spinal stabilization system having attached thereto a bone screw and a bone hook constructed in accordance with a first embodiment of the subject disclosure;

Fig. 2 is a perspective view of a locking cap which forms part of the bone screw and bone hook illustrated in Fig. 1, oriented in an inverted position for ease of illustration;

- Fig. 3 is a perspective view of the bone screw and locking cap of Fig. 1 separated from one another for ease of illustration;
  - Fig. 4 is a cross-sectional view of the bone screw of the subject disclosure taken along line 4-4 of Fig. 1;
  - Fig. 5 is a cross-sectional view of the locking cap taken along line 5-5 of Fig. 3;
- Figs. 6A through 6D illustrate operative steps associated with attaching the bone fastener of the subject disclosure to a spinal rod, wherein:
  - Fig. 6A illustrates the step of positioning the spinal rod and locking cap in the reception channel of the head portion of a fastening device of the subject disclosure;
  - Fig. 6B illustrates the initial orientation of the locking cap relative to the head portion of a fastening device of the subject disclosure wherein the locking cap is in an unlocked position;

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- Fig. 6C illustrates the rotation of the locking cap relative to the head portion of a fastening device of the subject disclosure to a partially locked position; and
- Fig. 6D illustrates the rotation of the locking cap relative to the head portion of a fastening device of the subject disclosure to a locked position;
  - Fig. 7 is a perspective view of a fastening device constructed in accordance with a second embodiment of the subject disclosure;
  - Fig. 8 is a perspective view of the fastening device of Fig. 7 with the locking cap separated for ease of illustration;
- Fig. 9 is a perspective view of the locking cap of the fastener device of

Fig. 7, oriented in an inverted position for ease of illustration; and

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Fig. 10 is a cross-sectional view of the fastening device of Fig. 7 taken along line 10-10 of Fig. 7.

These and other features of the apparatus disclosed herein will become more readily apparent to those having ordinary skill in the art from the following detailed description of the preferred embodiments taken in conjunction with the drawings.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings wherein like reference numerals identify similar structural elements of the subject apparatus, there is illustrated in Fig. 1 a section of a spinal stabilization system constructed in accordance with a preferred embodiment of the subject disclosure and designated generally by reference numeral 10.

Referring to Fig. 1, spinal stabilization system 10 includes an elongated spinal rod 12 having a circular cross-section and a substantially smooth outer surface finish. As illustrated, fastening devices in the form of a bone screw 14 and right-angle hook 16 are provided for securing spinal rod 12 to the spine during a spinal stabilization procedure. Both fastening devices employ a novel top-loaded locking cap, designated generally by reference numeral 20, which will be described in greater detail hereinbelow with reference to Fig. 2. The novel locking cap achieves significant clinical advantages over the prior art through its reliability and the ease in which it is installed during a spinal stabilization procedure.

It should be recognized that the subject disclosure is not limited in any way to the illustrated bone screw and right-angle hook. Rather, these particular fasteners are merely examples of the type of devices that can employ the novel locking cap disclosed herein. Other fasteners commonly utilized in spinal stabilization systems, such

as, for example, hooks having alternative angular geometries as well as clamps are also envisioned. Indeed, it is envisioned that any component designed for attachment to an elongated spinal rod or transverse coupling rod, may incorporate the novel locking cap of the subject disclosure. Also, any number of fastening devices can be applied along the length of the spinal rod.

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With continuing reference to Fig. 1, bone screw 14 includes a head portion 22 defining a horizontal axis and a vertical axis. A shank portion 24 depends from the head portion and a threaded portion 26 having a helical thread extending about the outer periphery depends from the shank portion. The helical thread is particularly adapted to securely engage the vertebral bodies of the spine. A channel 28 extends through the head portion 22 along the horizontal axis thereof for receiving elongated spinal rod 12. As best seen in Fig. 3, channel 28 is defined by the interior surfaces of side walls 30 and 32 and the curved lower surface 29 which extends therebetween. Locking cap 20 is dimensioned and configured for reception and engagement in locking channel 28 to secure the position of bone screw 14 with respect to spinal rod 12 during a spinal stabilization procedure.

Referring again to Fig. 1, right-angle hook 16 includes a head portion 42 defining a horizontal axis and a vertical axis. A hook portion 46 depends from the head portion 42 for securement to a vertebral body of the spine. A channel 48 extends through the head portion 22 along the horizontal axis thereof for receiving elongated spinal rod 12. Channel 48 is defined by the interior surfaces of opposed side walls 50 and 52 and a curved lower surface extending therebetween. Locking cap 20 is dimensioned and configured for reception and engagement in channel 48 to secure the position of hook 16 with respect to spinal rod 12 during a spinal stabilization procedure.

Referring now to Fig. 2, there is illustrated locking cap 20 in an inverted position to best illustrate structural aspects thereof. Locking cap 20 includes a cylindrical

and 78 are formed in the inner surfaces of opposed walls 30 and 32 for accommodating the cylindrical head 62 of locking cap 20 when the locking cap is received and rotated within channel 28.

The flanged portion 64 of locking cap 20 is defined in part by two diametrically opposed arcuate engagement flanges 82 and 84 which are dimensioned and configured for operative engagement with two complementary diametrically opposed arcuate engagement slots 86 and 88 defined in the interior surfaces of the opposed side walls 30 and 32 of head portion 22. (See Fig. 4).

With continuing reference to Figs. 3 through 5, engagement flanges 82 and 84 define ramped camming surfaces 92 and 94, respectively. Camming surfaces 92 and 94 are of opposite angular inclination with respect to one another. More particularly, each engagement flange has a low side (e.g., 82a of flange 82) and a high side (e.g., 82b of flange 82), whereby the low sides of the two flanges are diametrically opposed from one another as are the high sides. Actually, the camming surfaces of the flanges are mirror images of one another. Thus, the locking cap can be initially oriented with either flange aligned to engage either slot. This versatility adds to the ease in which the locking cap is installed during a surgical procedure.

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As best seen in Fig. 4, the arcuate engagement slots 86 and 88 in head portion 22 of fastener 14 have inclined surfaces which mate with the ramped camming surfaces 92 and 94 of flanges 82 and 84. As best seen in Fig. 5, the ramped camming surfaces 92 and 94 are tapered radially inwardly to enhance the interlock with the mating surfaces of arcuate engagement slots 86 and 88, which are also tapered to complement the radially inward taper of camming surfaces 92 and 94. This interlocking relationship serves to prevent the opposed side walls 30 and 32 of head portion 22 from spreading

radially outward as the arcuate flanges are engaged with the arcuate slots when the locking cap 20 is rotated to a locked position.

Figs 6A through 6D illustrate the steps in securing the fastening device to the spinal rod during a surgical procedure. Although attachment of a bone screw 14 is shown, it should be understood, as noted above, that other fastening devices, e.g., bone hooks, can be secured to the spinal rod 12 using the locking cap and head portion structure of the present disclosure. Initially, as illustrated in Fig. 6A, spinal rod 12 is moved into approximation with the horizontal channel 28 of head portion 22 such that the periphery of the spinal rod 12 is in registration with the curved surface 29 of the channel 28. Locking cap 20 is then top loaded into the channel along the vertical axis of the fastener in the direction of arrow a. At such a time, spinal rod 12 is accommodated within the elongate recess 68 defined in the bottom surface 66 of locking cap 20 and the bone screw 14 may be moved freely relative to the spinal rod. The opposed flanged sections 82 and 84 of locking cap 20 are 90° out of phase from the opposed arcuate engagement slots 86 and 88 defined in head portion 22, as shown for example in Fig. 6B.

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Thereafter, as shown in Fig. 6C, locking cap 20 is rotated 45° relative to head portion 22 about the vertical axis thereof. At such a time, spinal rod 12 is accommodated within one of the two transverse recesses 72 or 74, depending upon the initial orientation of the locking cap 20 with respect to the head portion. Thereupon, the opposed arcuate engagement flanges 82 and 84 of locking cap 20 are only partially engaged with the opposed arcuate engagement slots 86 and 88 defined in head portion 22, as they are 45° out of phase with the slots. Consequently, the locking cap holds the fastener 22 and spinal rod 12 together, but does not lock the fastener. In this position, the locking cap 20 can be readily rotated in the opposite direction to disengage from the spinal rod 12 to adjust the position of the bone screw 14 with respect to the spinal rod 12.

Once the desired position and orientation of the bone screw 14 has been attained, locking cap 20 is rotated another 45° to the locked position illustrated in Fig. 6D. At such a time, spinal rod 12 is accommodated within the orthogonal recess 70 defined in the bottom surface of locking cap 20. Thereupon, the opposed engagement flanges 82 and 84 of flanged portion 64 are fully engaged with the opposed engagement slots 86 and 88 of head portion 22, and the longitudinal and angular orientations of the bone screw 14 are fixed with respect to spinal rod 12, as illustrated in Fig. 4. It should be readily apparent that the manner and method by which bone screw 14 hook is attached to spinal rod 12 is identical to the manner and method by which hook 16 or other fasteners are attached to spinal rod 12.

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Since the rotational range of locking cap 20 is limited, i.e., the locking cap can only be rotated 90°, it will be readily appreciated that the cap cannot be over-torqued. Thus, the damage often caused by over-tightening a conventional threaded locking mechanism, such as a set screw, is avoided. Furthermore, since the locking cap of the subject disclosure has a predetermined locked position, it is unlikely that it will be undertorqued or left in a loose condition after installation as is common with threaded set screws found in the prior art. That is, by having a predetermined locked position, uniform locking forces are provided for all of the fastening devices used to secure the spinal rod 12 along its length and cross threading is reduced.

Referring now to Figs. 7 and 8, there is illustrated another fastening device constructed in accordance with a preferred embodiment of the subject disclosure and designated generally by reference numeral 110. Fastening device 110 is similar to fastening devices 12 and 14 in that it is particularly designed to facilitate securement of a spinal rod to the spine in a convenient manner. Fastening device 110 includes a head portion 122 having opposed side walls 130 and 132 which define a horizontal channel

Once the desired position and orientation of the bone screw 14 has been attained, locking cap 20 is rotated another 45° to the locked position illustrated in Fig. 6D. At such a time, spinal rod 12 is accommodated within the orthogonal recess 70 defined in the bottom surface of locking cap 20. Thereupon, the opposed engagement flanges 82 and 84 of flanged portion 64 are fully engaged with the opposed engagement slots 86 and 88 of head portion 22, and the longitudinal and angular orientations of the bone screw 14 are fixed with respect to spinal rod 12, as illustrated in Fig. 4. It should be readily apparent that the manner and method by which bone screw 14 hook is attached to spinal rod 12 is identical to the manner and method by which hook 16 or other fasteners are attached to spinal rod 12.

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Since the rotational range of locking cap 20 is limited, i.e., the locking cap can only be rotated 90°, it will be readily appreciated that the cap cannot be over-torqued. Thus, the damage often caused by over-tightening a conventional threaded locking mechanism, such as a set screw, is avoided. Furthermore, since the locking cap of the subject disclosure has a predetermined locked position, it is unlikely that it will be undertorqued or left in a loose condition after installation as is common with threaded set screws found in the prior art. That is, by having a predetermined locked position, uniform locking forces are provided for all of the fastening devices used to secure the spinal rod 12 along its length and cross threading is reduced.

Referring now to Figs. 7 and 8, there is illustrated another fastening device constructed in accordance with a preferred embodiment of the subject disclosure and designated generally by reference numeral 110. Fastening device 110 is similar to fastening devices 12 and 14 in that it is particularly designed to facilitate securement of a spinal rod to the spine in a convenient manner. Fastening device 110 includes a head portion 122 having opposed side walls 130 and 132 which define a horizontal channel

128 in conjunction with the curved lower surface 129 extending therebetween. Arcuate tabs 176 and 178 project upwardly from side walls 130 and 132, respectively, for interacting with locking cap 120.

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Referring to Fig. 9, locking cap 120, which is shown in an inverted position for ease of illustration, includes a hexagonal head 162, a cylindrical body 163 and a flanged portion 164. The hexagonal head 162 is adapted and configured for interaction with a wrench or similar work implement. An annular channel 165 extends into the bottom surface of hexagonal head 162 for receiving arcuate tabs 176 and 168. This positive interaction serves to prevent the opposed side walls 130 and 132 of head portion 122 from spreading radially outwardly when arcuate flanges 182 and 184 of locking cap 120 are engaged in arcuate slots 186 and 188 of head portion 122 upon rotation of locking cap 20 into a locked position. Thus, in this embodiment, the ramped camming surfaces 192 and 194 of the arcuate engagement flanges 182 and 184 need not be provided with radially inwardly directed tapers as provided on flanges 82 and 84 of the locking cap 20 of the embodiment of Figs. 1-6.

With continuing reference to Fig. 9, the bottom surface 166 of the flanged portion 164 of locking cap 120 is configured in substantially the same manner as the bottom surface 66 of locking cap 20 in that it is provided with an elongate recess 168 for accommodating a spinal rod when the locking cap 120 is in an unlocked position, first and second bifurcated transverse recesses 172 and 174 which intersect the elongate recess 168 at opposite 45° angles to accommodate the spinal rod when the locking cap 120 is in either of two intermediate positions, and a bifurcated orthogonal recess 170 which intersects the elongate recess at a 90° angle to accommodate the spinal rod when the locking cap 120 is in a final locked position, as shown in Fig. 10. It will be readily appreciated that locking cap 120 is engaged with fastening device 110 in a manner that is

substantially similar to the manner in which locking cap 20 is engaged with bone fastener 14 and hook 16, and that the configuration of the bottom surface of flanged portion 164 provides the same benefits afforded by the flanged portion 64 of locking cap 20.

Although the apparatus disclosed herein has been described with respect to

5 preferred embodiments, it is apparent that modifications and changes can be made thereto
without departing from the spirit and scope of the invention as defined by the claims.

## WHAT IS CLAIMED IS:

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1. A device for securing a spinal rod to the spine comprising:

- a) a head portion configured to receive a spinal rod;
- b) a locking cap configured to engage the head portion and the spinal
- 5 rod upon rotation of the locking cap relative to the head portion to secure the position of the head portion relative to the spinal rod; and
  - c) a fastener portion depending from the head portion and configured to engage the spine.
- 10 2. A device as recited in Claim 1, wherein the head portion has a channel extending therethrough for receiving a spinal rod and the channel is bounded by opposed side walls.
- 3. A device as recited in Claim 2, wherein each of the opposed side walls has an arcuate engagement slot defined therein.
  - 4. A device as recited in Claim 3, wherein the locking cap has opposed arcuate engagement flanges configured for reception in the opposed arcuate engagement slots of the head portion upon rotation of the locking cap relative to the head portion.
  - 5. A device as recited in Claim 4, wherein the locking cap is configured for rotation between an initial position in which the arcuate engagement flanges are 90° out of phase with the arcuate engagement slots, an intermediate position in which the arcuate engagement flanges are 45° out of phase with the arcuate engagement slots and a locked position in which the arcuate engagement flanges are in phase and intimately engaged with the arcuate engagement slots.

6. A device as recited in Claim 5, wherein the bottom surface of the locking cap includes an elongate recess oriented to accommodate a spinal rod when the locking cap is in an initial position.

7. A device as recited in Claim 6, wherein the bottom surface of the locking cap includes an orthogonal recess which intersects the elongate recess at a 90° angle to accommodate a spinal rod when the locking cap is in a locked position.

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- 8. A device as recited in Claim 6, wherein the bottom surface of the locking cap includes at least one transverse recesses which intersects the elongate recess at a 45° angle to accommodate a spinal rod when the locking cap is in an intermediate position.
- 9. A device as recited in Claim 1, wherein the locking cap has acylindrical head which includes a hexagonal bore for receiving a work implement.
  - 10. A device as recited in Claim 1, wherein the locking cap has a a hexagonal head configured for reception by a work implement.
- 20 11. A device as recited in Claim 3, wherein the opposed engagement slots are each defined in part by inclined slot surfaces, with the angle of the inclined slot surface of one engagement slot being opposite that of the opposed engagement slot, and wherein the opposed engagement flanges are each defined in part by inclined flange surfaces, with the angle of the inclined flange surface of one engagement flange being opposite that of the opposed engagement flange.

12. A device as recited in Claim 11, wherein the inclined slot surfaces and the inclined flange surfaces are angularly tapered to complement each other.

- 13. A device as recited in Claim 1, wherein the fastener portion is configured as a screw.
  - 14. A device as recited in Claim 1, wherein the fastener portion is configured as a hook.
- 10 15. A device for securing a spinal rod to the spine comprising:

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- a) a head portion defining a vertical axis and a horizontal axis, and configured to receive a spinal rod along the horizontal axis;
- b) a locking cap configured for reception by the head portion along the vertical axis, and adapted to engage the head portion and the spinal rod upon rotation of the locking cap about the vertical axis to secure the position of the head portion relative to the spinal rod; and
  - c) a fastener portion depending from the head portion and configured to engage the spine.
    - 16. A device for securing a spinal rod to the spine comprising:
- a) a head portion having a channel extending therethrough for receiving a spinal rod;
- a locking cap configured to cooperate with the channel and engage the spinal rod of the locking cap/being rotatable relative to the head portion between an
   unlocked position and a locked position to secure the position of the head portion relative to the spinal rod;/and

c) a fastener portion depending from the head portion and configured to engage the spine.

- A device as recited in Claim 16, wherein the locking cap is
   configured for rotation from the unlocked position to a partially locked intermediate position.
- 18. A device as recited in Claim 16, wherein the channel is bounded by opposed side walls each having an arcuate engagement slot defined therein, and the locking cap has opposed arcuate engagement flanges configured for reception in the opposed arcuate engagement slots upon rotation of the locking cap into the locked position.
- bottom surface which includes an elongate recess oriented to accommodate a spinal rod when the locking cap is in the unlocked position, an orthogonal recess which intersects the elongate recess at a 90° angle to accommodate a spinal rod when the locking cap is in the locked position, and at least one transverse recesses which intersects the elongate recess at a 45° angle to accommodate a spinal rod when the locking cap is in the partially locked intermediate position.
  - 20. A device as recited in Claim 18, wherein the opposed engagement slots are each defined in part by inclined slot surfaces, with the angle of the inclined slot surface of one engagement slot being opposite that of the opposed engagement slot, and wherein the opposed engagement flanges are each defined in part by inclined flange

surfaces, with the angle of the inclined surface of one engagement flange being opposite that of the opposed engagement flange.

- 21. A device as recited in Claim 20, wherein the inclined slot surfaces
  and the inclined flange surfaces are angularly tapered to complement each other.
  - 22. A device as recited in Claim 16, wherein the fastener portion is configured as a screw.
- 10 23. A device as recited in Claim 16, wherein the fastener portion is configured as a hook.

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- 24. A device for securing a spinal rod to the spine comprising:
- a) a head portion having a channel extending therethrough for

  15 receiving a spinal rod, the channel being bounded by opposed side walls, each side wall having an arcuate engagement slot defined therein.
  - b) a locking cap having a bottom surface configured to accommodate a spinal rod extending through the channel of the head portion/and including opposed arcuate engagement flanges configured for reception in the opposed arcuate engagement slots of the head portion upon rotation of the locking cap relative to the head portion to secure the position of the head portion relative to the spinal rod; and
  - c) a fastener portion depending from the head portion and configured to engage the spine.
- 25. A device as recited in Claim 24, wherein the locking cap is configured for rotation between an initial position in which the arcuate engagement flanges are 90° out of phase with the arcuate engagement slots, an intermediate position

in which the arcuate engagement flanges are 45° out of phase with the arcuate engagement slots and a locked position in which the arcuate engagement flanges are in phase and intimately engaged with the arcuate engagement slots.

- 5 26. A device as recited in Claim 24, wherein the bottom surface of the locking cap includes a first recess oriented to accommodate a spinal rod when the locking cap is in the initial position.
- 27. A device as recited in Claim 24, wherein the bottom surface of the locking cap includes a second recess which intersects the first recess at a first angle to accommodate a spinal rod when the locking cap is in the locked position.
  - 28. A device as recited in Claim 24, wherein the bottom surface of the locking cap includes a third recess which intersects the first recess at a second angle to accommodate a spinal rod when the locking cap is in the intermediate position.
  - 29. A device as recited in Claim 26, wherein the first recess is an elongate recess.
- 20 30. A device as recited in Claim 27, wherein the second recess intersects the first recess at a 90° angle.

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- 31. A device as recited in Claim 28, wherein the third recess intersects the first recess at a 45° angle.
- 32. A device as recited in Claim 24, wherein the channel is defined in part by a hemi-cylindrical seat for accommodating a cylindrical spinal rod.

33. A device as recited in Claim 24, wherein the locking cap includes a cylindrical head having a hexagonal bore defined therein for receiving a work implement.

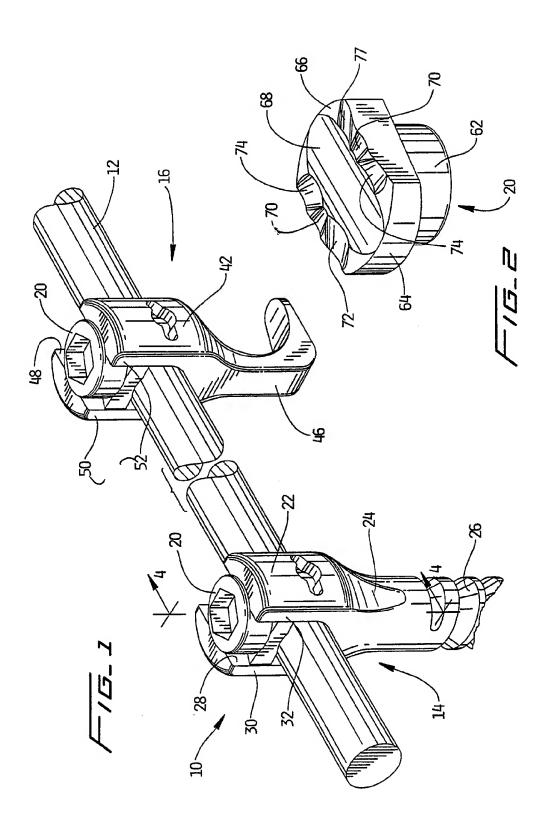
- 5 34. A device as recited in Claim 33, wherein the opposed side walls of the head portion include opposed arcuate notches for accommodating the cylindrical head of the locking cap.
- 35. A device as recited in Claim 24, wherein an arcuate appendage
   projects upwardly from each side wall of the head portion to engage an annular recess formed in an upper portion of the locking cap.
  - 36. A device as recited in Claim 35, wherein the upper portion of the locking cap has a hexagonal configuration for reception by a working implement.

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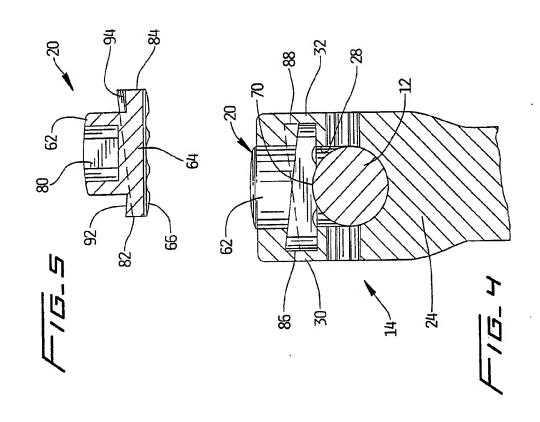
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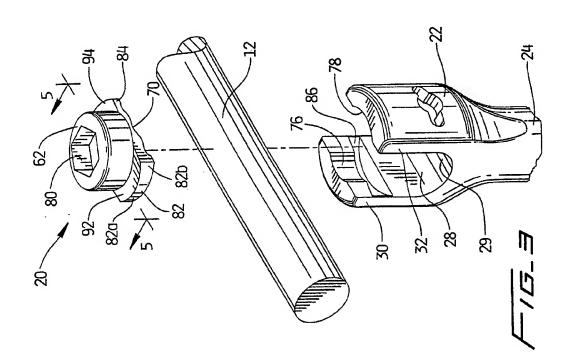
- 37. A device as recited in Claim 24, wherein the opposed engagement slots are each defined in part by inclined slot surfaces, with the angle of the inclined slot surface of one engagement slot being opposite that of the opposed engagement slot, and the opposed engagement flanges are each defined in part by inclined flange surfaces, with the angle of the inclined flange surface of one engagement flange being opposite that of the opposed engagement flange.
- 38. A device as recited in Claim 37, wherein the inclined slot surfaces and the inclined flange surfaces are angularly tapered to complement each other.
- 39. A device as recited in Claim 24, wherein the fastener portion is configured as a bone screw.

40. A device as recited in Claim 24, wherein the fastener portion is configured as a bone hook.

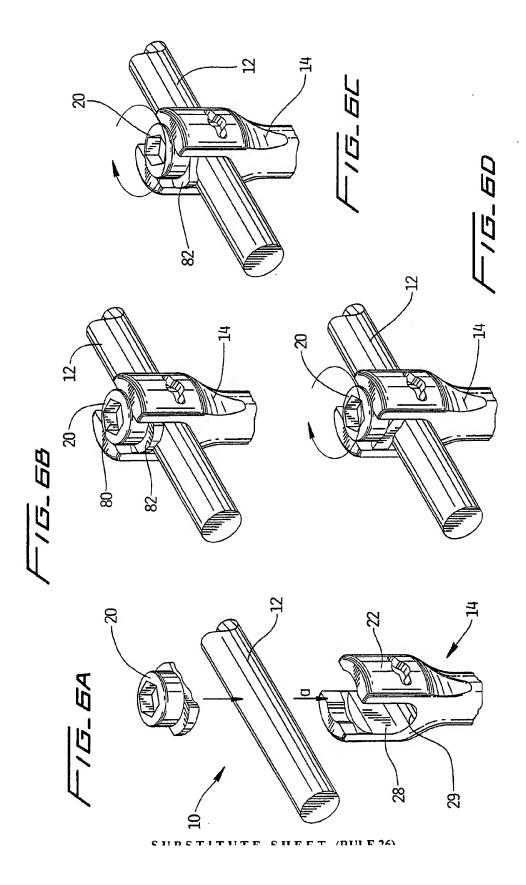


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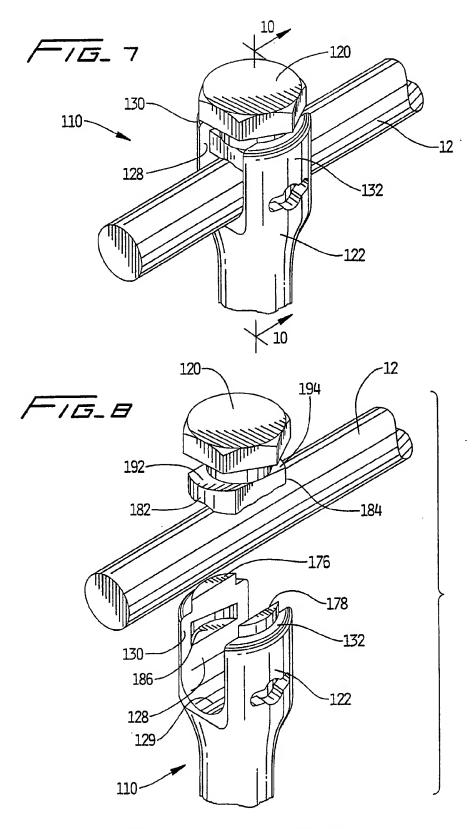


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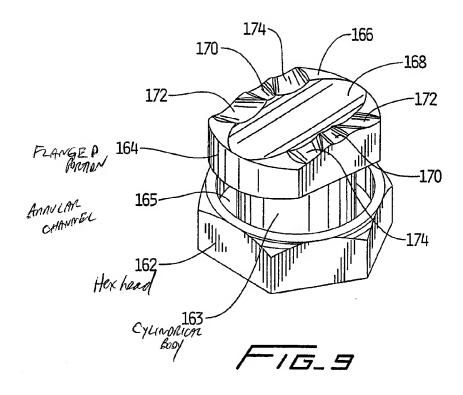
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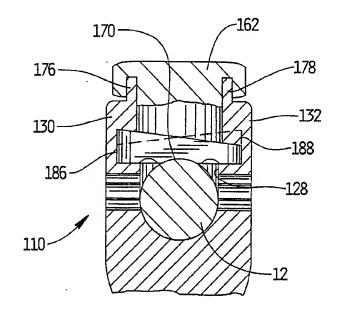
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## INTERNATIONAL SEARCH REPORT

Inte onal Application No PCT/US 99/22860

	PC1/		PC1/US 99/22860	
A. CLASSIF IPC 7	FICATION OF SUBJECT MATTER A61B17/70			
A exercise to	o International Patent Classification (IPC) or to both national cla	ssification and IPC		
	SEARCHED	SSINGARON AND IN CO.		
	ocumentation searched (classification system followed by class A61B	fication symbols)		
Documentat	tion searched other than minimum documentation to the extent	that such documents are incl	uded in the fields searched	
Electronic d	lata base consulted during the international search (name of da	la base and, where practica	. search terms used)	
C. DOCUME	ENTS CONSIDERED TO BE RELEVANT			
Category '	Citation of document, with indication, where appropriate, of the	Relevant to claim No.		
X	US 5 562 663 A (WISNEWSKI PAUL J ET AL) 8 October 1996 (1996-10-08)		1-4,13, 16,18, 22,24, 32,39	
A	the whole document		5,6,15	
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